Assessment of Eustachian tube functioning following surgical intervention of Oral Submucous Fibrosis by using tympanometry & audiometry

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ABSTRACT

Oral Submucous fibrosis has been reported to cause variation in hearing sensitivity & changes in middle ear function. This study was conducted to validate the influence of OSMF and its surgical correction on middle ear function and hearing sensitivity. In this study, 20 patients (40 ears) suffering from biopsy proven OSMF (Group 2 & 3) were tested for Middle ear dysfunction and hearing sensitivity using Tympanometry & Audiometry. On Tympanometry, Type A curve was obtained in 29 ears, Type B curve in 11 ears preoperatively. Immediate postoperatively TYPE A curve was obtained in 27 ears, TYPE B curve in 13 ears. After 1 month and 3 month Type B curve was not obtained in any ear. On Audiometry, 28 ears showed normal hearing and 12 ears showed minimal conductive hearing loss preoperatively and Immediate postoperatively. Tests after 1 month and 3 months showed all 40 ears having normal hearing. Results were found statistically significant with p value 0.000 and F value of 11.331 in Tympanometry and 11.143 in Audiometry. Pearson correlation test revealed that results from both the test are highly co related (0.902). OSMF causes fibrotic changes in paratubal muscles which in addition with restricted mouth opening hampers proper Eustachian tube functioning in turn causing changes in Middle ear function. This feature is seldom/infrequently found in Group 2 and 3 and if encountered can be dealt effectively with surgical intervention.

1. Introduction

Oral Submucous Fibrosis (OSMF) is a chronic, progressive, scarring precancerous condition, widespread in South East Asian population. It is linked with the chronic placement of betel quid in the mouth.^{1–4}

Clinical features include inadequate mouth opening, blanching of oral mucosa, stomatopyrosis, xerostomia, dysphagia. Progressive inability to open the mouth is due to loss of elasticity & development of vertical fibrous bands in labial and buccal tissues. This disease is commonly seen in adults & adolescents especially in the ages between 16 and 35 years. It may be associated with other precancerous lesions and conditions.^{1–4} Besides these clinical features, middle ear/Eustachian tube (ET) dysfunction has been documented in advanced

stages of OSMF.^{2,3,5,6} Several studies in the past have investigated the association of OSMF with Eustachian tube dysfunction. Most of the studies included patients suffering from OSMF – Khanna and Andrade Group 4. However, in this study we have tried to find out, the prevalence of ET dysfunction in patients suffering from biopsy proven Oral Submucous fibrosis (Khanna and Andrade Group 2 & 3). Also, no study appears to have compared the changes of Eustachian tube functioning following surgical intervention of OSMF with that of pre surgical Eustachian tube functioning. Hence, the second objective of this study was to detect whether the surgical release of fibrous bands is of any help to treat hearing problems in such patients.

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2. Materials and method

2.1. Study design

This was an observational prospective study conducted at Manipal College of Dental Sciences, Manipal, Karnataka, India by Department of Oral & Maxillofacial Surgery, between Jan 2015 to July 2016 on 20 otherwise systemically healthy OSMF patients after obtaining ethical clearance from the Institutional ethical committee, Kasturba Hospital, Manipal. Therefore, the sample size included 40 ears.

2.2. Participant selection criteria

Inclusion Criteria:

- All patients with biopsy proven OSMF & reduced opening of the mouth.
- Patients in Group 2 & Group 3 according to Khanna JN, Andrade NN (1995) classification – with the mouth opening of 15–35 mm.

Exclusion Criteria:

- Patients in Group 4A & 4B according to Khanna JN, Andrade NN (1995)
- Presence of any other oral lesions and any other etiology for trismus eg. TM Joint problems
- Patients who refuse to undergo ear test, fail to come for follow up
- Patients who do not comply with postoperative instructions
- Patients with hearing aids, pre-existing ear infections

2.3. Equipments

- a. Interacoustics AC - 40 Clinical Audiometer (Fig. 1A): A duly calibrated (ANSI S3.43-1996) double channel diagnostic audiometer coupled with TDH-50P earphones was used to obtain air conduction thresholds. Bone conduction thresholds were obtained using Radio ear B-71 bone vibrator. This instrument was used to determine the degree, type, pattern of the loss.
- b. GSI Tymstar Impedance audiometer/Tympanometer (Fig. 1B): A calibrated (ANSI 3-39-1987) immittance meter was used to assess the middle ear status of the client.

2.4. Procedure

Patients with reduced mouth opening were assessed clinically and undertaken for biopsy under local anesthesia to confirm the presence Oral Submucosa fibrosis. The biopsy was done from multiple sites to rule out field cancerisation. Once biopsy confirmed the presence of Oral Submucosa fibrosis, patients were explained regarding the procedure in the language they understand and informed consent was taken. Patients were taken up for surgery under General anesthesia (GA), for release of

Fig. 1a. Interacoustics AC-40 clinical audiometer.

Fig. 1b. GSI Tymstar impedance audiometer/Tympanometer.

Fig. 2. Release of fibrous bands and reconstruction using buccal fat pad and collagen sheet.

fibrous bands in bilateral buccal mucosa with reconstruction using buccal fat pad & collagen sheet (Fig. 2). Following the surgery the treatment was supplemented by rigorous mouth opening exercises, surface ultrasound or intralesional steroid with hyaluronic acid as per patient's requirements.

2.5. Evaluation

Tympanometry and Audiometry was done in the presurgical phase and in the postsurgical phase. A total of 3 readings were taken in the postsurgical phase – one day after surgery, 1month after surgery, 3months after surgery. The tests were done by the Department of Speech & Audiology, School of Allied Health Sciences, Manipal.

Statistical analysis.

- These recordings were noted in Window 10 Microsoft excel sheet.
- The results were analysed using SPSS (Statistical Package for the Social Sciences) version 20.0 (Chicago, USA) software in the Department of Statistics, Manipal academy of Higher Education
- One way ANOVA and Post Hoc Test was done to find out the statistical significance of the findings.
- Pearson correlation test was done to find the correlation between the results obtained from tympanometry and audiometry.

3. Result

Out of 40 ears Type A curve/normal Tympanometric curve was obtained in 29 ears (0.725), Type B curve/abnormal Tympanometric curve was obtained in rest 11 ears (0.275) preoperatively. Immediate postoperative Tympanometry test showed TYPE A curve in 27 ears (0.675) TYPE B curve in 13 ears (0.325). Tympanometric test after 1 month revealed that Type B curve was not obtained in any ear and all 40 ears showed Type A curve. The same result was obtained 3 months postoperatively. Post Hoc test revealed that an increase of 2 ears showing Type B curve on tympanometry in the immediate

CHANGE IN MIDDLE EAR FUNCTION DUE TO ET TUBE DISTURBANCE

Fig. 3. Bar graph representation of results.

postoperative period in relation to the preoperative period is statistically not significant (1.000).

On Audiometric Test, out of 40 ears, 28 ears (0.7) showed normal hearing and 12 (0.3) ears showed minimal conductive hearing loss preoperatively. Audiometric test done on the immediate postoperative day showed the same. The test was done after 1 month, showed all 40 ears having normal hearing. (Results are depicted in Fig. 3). The same result was obtained 3 months postoperatively. One way ANOVA was done and the results were found statistically significant with p value 0.001 in both tests and F value of 11.331 in Tympanometric test and 11.143 in Audiometric test.

Pearson correlation test shows that both test methods are highly correlated (0.902). None of the ears at any stage showed a mild, moderate, moderately severe, severe or profound hearing loss on audiometric analysis.

4. Discussion

4.1. Proposed pathophysiology

ET serves as a mediator between oral cavity and middle ear. ET physiologically has negative pressure and is usually collapsed. It mainly equilibrates pressure of the middle ear with that of atmospheric pressure. A repeated intermittent opening of the Eustachian tube takes place by active contraction of the tubal & paratubal muscles especially tensor veli palati when we are swallowing to maintain ambient pressure.^{5,6}

It is postulated that atrophic & degenerative changes spreading to these muscles hamper ET patency and alters middle ear properties. Possibly there is a loss of elasticity of these muscles due to fibrotic and scarring changes, as a result of which negative pressure increases, tympanic membrane is sucked in and its shape changes. This collectively hinders sound conduction and hence hearing impairment.^{5,6}

On the other hand, since mandibular movements are restricted in OSMF it inhibits patient to open mouth or swallow properly. As a result, the active opening of ET does not happen.

4.2. The Tympanometer and the audiometer

Tympanometer/Middle ear analyser assesses middle ear functioning

and measures the movement, or compliance, of the eardrum/tympanic membrane as air pressure is increased or decreased in the ear canal.⁵ Results are plotted on a graph called a tympanogram and categorized as either a Type A, B, or C (Fig. 4A). Type A refers to eardrum movement within normal limits. Type B indicates little or no eardrum movement. Type C refers to a middle ear with negative pressure which is indicative of Eustachian tube dysfunction. Such a tympanogram may be caused by retraction of the eardrum or blockage of the Eustachian tube. Presence of 'C' type tympanogram is the strong indicator of Eustachian tube occlusion or obstruction leading to negative pressure in the middle ear successively leading to 'B' type Tympanogram⁵⁻⁷

Audiometer uses air and bone conduction to determine hearing sensitivity within frequencies 250 Hz to 8 kHz (Fig. 4B). Along the horizontal X-axis of the graph lies the frequency in Hertz and along the vertical Y-axis lies the intensity in Decibels.^{4,6,7} Results are plotted and categorized into different degrees of hearing loss using Goodman's classification (1952).^{4,5,7}

- Normal Hearing: 0dB–15dB
- Minimal Hearing Loss: 16 dB– 25 dB
- Mild Hearing Loss: 26 dB–40 dB
- Moderate Hearing Loss: 41 dB–55 dB
- Moderately Severe Hearing Loss: 56–70 dB
- Severe Hearing Loss: 71 dB–90dB
- Profound Hearing Loss: > 90 dB

Many researchers in the past have evaluated the involvement of fibrotic changes in paratubal muscles in OSMF and its relationship with Eustachian tube functioning using the above-mentioned test.

Gupta et al. in the year 2000 studied histopathological changes in paratubal & tubal muscles in OSMF. Dysplasia was noticed in 13.2% of patients. Degenerative changes in palatal/paratubal muscles were found in the form of loss of cross striation in 13.2%, edematous muscle fibres in 9.4% of cases. It was concluded that there was definite involvement of palatal/paratubal muscles in OSMF.⁸

In a study by S.C. Gupta, Mangal Singh, Sanjay Khanna, Sachin Jain, 21% of total patients had an abnormal hearing on audiometry and 20% patients had TYPE B curve on tympanometry.⁹ Alagiri Chandran, Nalini Aswath suggested that in Grade 3 OSMF about 43% of the patients

Fig. 4. a Sample graphs of tympanometry (Type A – Eardrum movement in normal limits, TYPE B – Little or no eardrum movements, TYPE C – Eustachian tube dysfunction due to negative pressure). b Sample graph of audiometry (Normal Hearing: 0dB–15dB, Minimal Hearing: 16 dB– 25 dB, Mild Hearing loss: 26 dB–40 dB, Moderate Hearing Loss: 41 dB–55 dB, Moderately Severe Hearing: 56–70 dB, Severe Hearing Loss: 71 dB–90dB, Profound Hearing Loss: > 90 dB).

showed positive audiogram results and 47% showed positive Tympanometric results.¹⁰ In a recent paper by Sowbhgya *et al* 21% of patients had hearing impairment on audiometry, and the statistical correlation was significant.¹¹ Shanti Badra *et al.* suggested that patients with grade III OSMF had bilateral mild Conductive hearing loss.¹² Maulik Shah, Ashish Katarkar, Pankaj Shah, Noorain Alam, Datt study suggested, a significant association between OSMF and Eustachian tube function.

This implies while treating OSMF, its effect on ET functioning and possible middle ear changes should be kept in mind.¹³

Our present study concluded a similar result. Approximately 30% of total patients suffering from OSMF (GRADE II and III) were positively tested by audiometry and tympanometry in preoperative period suggestive of hearing deficit.

In a study conducted by Sana-Noor Siddiqui, Nisheeth Saawarn, Preeti P. Nair, Pooja Singh, Harshkant P. Gharote, Karthik Hegde, Audiometric and Tympanometric analysis showed no significant differences in hearing abilities of OSMF patients and controls and between

various grades of OSMF, indicating no hearing impairment. On the other hand, the Eustachian tube function test revealed a statistically significant difference in Eustachian tube function in OSMF patients and controls. Further, there was a significant increase in the severity of dysfunction with an increase in the severity of the disease. This study concluded that the ET may be affected by the disease process. But, probably the amount of deviation found in function of the Eustachian tube is non-contributing to cause a conductive hearing loss.¹⁴

None of the above mentioned studies compared the Eustachian tube functioning and middle ear status in the postoperative period with that of preoperative results. In this study, after the 20 patients were confirmed by biopsy, they were undertaken for bilateral surgical release of intraoral fibrous bands under General anesthesia. Post surgically there was gradual improvement in mouth opening. With increase in mouth opening, jaw movements became more active and the patient was able to swallow better. This caused active opening and better ventilation of Eustachian tube and hence Middle ear functioning improved, as

suggested by tympanometry and audiometry findings. Since the improvement in mouth opening was gradual, Middle ear changes was even gradual and not immediately after the surgery. No statistical significance in improvement was found in immediate postsurgical readings. However readings of tympanometry and audiometry in 1 month postop and 3 month postop showed 100% improvement in hearing function. This improvement was statistically significant.

Only 1 patient (2 ears) who had normal tympanogram & audiogram reading preoperatively gave type B curve on tympanometry in 1 day postoperative period. However, his audiogram continued to show normal hearing in 1 day postoperative period. After 1 month of follow up, both tympanometry & audiometry showed normal outcomes and same in 3 months follow up.

This event is however statistically insignificant and may be due to following causes:

1. Test procedural variations and Error in recording
2. The Patient can have a cold & cough causing mild middle ear effusion/otitis media which could have resolved spontaneously with time.

Therefore it can be concluded that surgically it is not possible to release the fibrosis in tubal & paratubal muscles or reverse the histopathological changes that have already affected the region. However, we can at least aim to provide the patient a better mouth opening so that swallowing improves & in turn actively opens eustachian tube each time. This improves the Middle ear function even if underlying histopathological changes still persist in paratubal muscle.

4.3. Therefore clinical implication can be

1. The Routine practice of implementing audiological test protocol for Oral Sub mucosal fibrosis
2. Audiological tests can provide prognostic indicators for the conducted surgical procedure.

4.4. Drawbacks of the study

- 1 The sample size is small
- 2 Follow up period is 3 months

4.5. Strengths of the study

1. A relation between the occurrence of ET defects and Middle ear function with OSMF Group 2 and 3 is evaluated which was not attempted by any literature available till date. Presence of such features supports the fact that subclinical submucosal fibrotic changes

- of paratubal and tubal muscles may be present in these groups.
2. None of the studies till date evaluates ET functioning and middle ear functioning in the post operative phase.

Ethics statement

The study underwent ethical clearance from the Institutional Ethical Committee, Kasturba Hospital, Manipal (Registration no. ECR/146/Inst/KA/2013) with IEC no. 04/2015. The patients were informed according to the Adult Participation information sheet and consent was duly taken on Adult Informed Consent formed as provided by the IEC.

Declaration of competing interest

We have no conflict of interest.

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