A study on Eustachian Tube Dysfunction after Tympanoplasty in Chronic Otitis Media mucosal disease

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Structured Abstract

Introduction: Good eustachian tube function (ETF) is one of the most important factor deciding the hearing outcome following tympanoplasty for chronic otitis media (COM) mucosal disease. However, assessment of eustachian tube function is not easy in the presence of a perforated tympanic membrane. This study aims to find out the proportion of patients with postoperative eustachian tube dysfunction (ETD) after tympanoplasty and to find the risk factors for post operative eustachian tube dysfunction in tympanoplasty for COM.

Materials and Methods: This is a prospective observational study, conducted from 1rst November 2017 to 31rst May 2019 in the Department of ENT, Government Medical College, Thiruvananthapuram. 105 consecutive patients with COM mucosal disease, who underwent tympanoplasty with or without cortical mastoidectomy, were included in the study and followed up for a period of 3 months and Eustachian tube function assessed. The patients with eustachian tube dysfunction were compared with those with normal eustachian tube function to identify the factors significant in the development of post-operative Eustachian tube dysfunction.

Results: Out of the 105 cases studied, the proportion of patients with post-operative eustachian tube dysfunction was 49.5%. The risk factors significantly associated with post operative eustachian tube dysfunction were history of sino nasal disease, nasal allergy, abnormal ETF in contralateral ear and abnormal results of Toynbee test in preoperative Tympanometry for analyzing ETF in perforated tympanic membrane.

Conclusion: Hence, we would like to consider above mentioned risk factors as predictive factors of post-operative ETD. Good ETF was also associated with better hearing outcome, compared with patients with ETD.

Keywords: Post-operative eustachian tube dysfunction; Tympanoplasty; Chronic otitis media; Impedance Audiometry.

Introduction
The eustachian tube is a complex dynamic organ consisting of a mucosa lined canal, surrounded by cartilage, soft tissues, bony supports and sphenoid sulcus. The eustachian tube ventilates the middle ear, regulates middle ear pressure, clears...
secretions from middle ear, damps nasopharyngeal sound pressure and prevents reflux of nasopharyngeal secretions. The eustachian tube thus plays a vital role in middle ear function and eustachian tube dysfunction (ETD) leads to multiple middle ear pathologies and hearing loss. A normally functioning eustachian tube is considered a major positive prognostic factor in the success of tympanoplasty surgery. Hence, the assessment of eustachian tube function is of prime importance before undertaking any surgical procedures for chronic otitis media. But unfortunately, methods for precisely measuring preoperative eustachian tube function in the presence of a perforated tympanic membrane are inadequate. Many methods have evolved over time to evaluate eustachian tube function but most of them are complex, invasive and are not available in many places. There are various factors that can predispose to ETD like sino nasal disease, nasal allergy, deviated nasal septum, laryngopharyngeal reflux disease etc. This study aims on finding out the proportion of eustachian tube dysfunction after tympanoplasty and to find out various factors that are significantly associated with postoperative eustachian tube dysfunction and to assess audiological outcome in relation to eustachian tube function.

Methods and Materials
This is a prospective observational study conducted in patients with chronic otitis media mucosal disease and underwent tympanoplasty in the Department of ENT, Government Medical College, Trivandrum from November 2017 to September 2019. This study was conducted after obtaining approval of Institutional ethical committee. Minimum sample size for the study was calculated to be 100. Patients with chronic otitis Media mucosal disease both active and inactive, who underwent tympanoplasty, in the age group 12 years to 60 years were included in the study. Patients with chronic Otitis Media mucosal disease secondary to tumors of nasopharynx or middle ear and patients who underwent revision tympanoplasty surgery were not included in the study. In addition, those patients for whom there was inability to achieve prob seal in tympanometry, thereby making it impossible to perform tympanometric assessment of eustachian tube function, were also excluded. 105 consecutive patients were included in the study after obtaining informed consent. Data regarding sociodemographic factors, co-morbidities, perforation size, middle ear status, ossicular status, surgical approach, nasal pathologies, status of contralateral ear, type of tympanoplasty performed, type of graft, whether combined with cortical mastoidectomy or not, were collected. Pure tone audiometry (PTA) and tympanometry were performed using Audiometer (ALPS AD 2000) and tympanometer (GSI Tymstar). In the presence of perforated tympanic membrane tympanometric Toynbee test was done. Bluestone’s nine step inflation deflation test and modified inflation deflation test were not done as they were not available in our institution.

Tympanometric Toynbee test\textsuperscript{[1]}: In this test, the impedance audiometer is programmed to artificially increase or decrease the air pressure at middle ear. The probe is placed in the external ear canal, and pressure changes in the middle ear were recorded, while the patient is asked to perform the Toynbee maneuver three times in 80 seconds\textsuperscript{[2]}. For each maneuver, the opening (O1, O2, O3) and closing (C1, C2, C3) pressures are measured. This change in air pressure is recorded graphically by the impedance audiometer. Normally, with three or four swallows the middle ear pressure should totally neutralize ie it should reach 0 daPa. Partial impairment is considered, if some residual pressure persists even after five swallows (Figure 1). If the pressure built up by the impedance audiometer cannot be neutralized at all by repeated swallowing, then ETF considered to be grossly impaired.
Figure 1: Toynbee test in Tympanometry showing partial ET dysfunction

Diagnostic nasal endoscopy and high resolution CT scan of the temporal bone were done for all patients prior to surgery. Patients were given routine postoperative care including antibiotics for seven days. Patients requiring antiallergic treatment were treated using antihistamines and steroid nasal sprays. Septoplasty was carried out in patients with obstructed deviated nasal septum at least 6 weeks prior to tympanoplasty. Patients were followed up at 12 weeks to assess the status of tympanic membrane. PTA and tympanometry were done to assess the audiological outcome as well as for assessment of middle ear dynamics. Postoperative improvement or good eustachian tube function was considered if there was an intact tympanic membrane and A curve on tympanometry. Postoperative eustachian tube dysfunction was considered if patient had graft failure with residual perforation or tympanometry showing B or C curve. Pre-operative and operative details of the patients with good and poor eustachian tube function were compared to identify any possible risk factors.

Statistical Analysis: Categorical and quantitative variables were expressed as frequency (percentage) and mean ± two standard deviation respectively. Independent t test and one-way ANOVA test was carried out to compare quantitative data among groups. Chi square test was used to find association of post-operative ETF with selected qualitative variables. Independent t test was carried out to find improvement in PTA based on post operative ETF. P < 0.05 was considered the threshold for statistical significance. Statistical analyses were performed by using the statistical software package SPSS, version 20.0.

Results and Analysis
105 clinically diagnosed cases of Chronic otitis media mucosal disease who underwent Tympanoplasty with or without Cortical Mastoidectomy were studied. Relevant findings noted from study are as follows.

Among 105 patients, male: female ratio was 1:1.5. The mean age of presentation was 30.9 years and majority of patients (29.5%) were between 20 and 29 years. Age and socioeconomic factors did not have any significant association with postoperative Eustachian tube function. Ear discharge (92.4%) and hearing loss (66.7%) were the most common complaints on presentation. The comorbidities in the study group were hypertension (9.5%) and diabetes mellitus (8.6%).15.2% of the study population were smokers and 12.4% were consuming alcohol. Neither co morbidities nor habits had any significant effect on postoperative Eustachian tube function. 70.5% had unilateral COM mucosal disease out of which 46.7% had normal contralateral ear and 23.8% had Eustachian tube dysfunction in contralateral ear. 38.1% had active disease and rest had inactive disease. 29.5% had bilateral chronic otitis media mucosal disease. Eustachian tube disease in contralateral ear was found to be significantly associated with post operative Eustachian tube dysfunction (p 0.01). 18 patients (17.1%) had history of sino nasal disease, which included chronic sinusitis and sino nasal polyposis. These patients were given medical treatment and underwent Endoscopic sinus surgery when indicated well ahead of ear surgery (at least 6 weeks prior). Sinonasal disease was found to be significantly associated with post operative Eustachian tube dysfunction (p 0.02). 22.9% had history of nasal allergy and was found to be significant (p 0.017). 23 patients (22%) had obstructed nasal deviation and underwent septoplasty at least 6 weeks prior to ear surgery.
Only twelve patients (11.4%) had laryngopharyngeal reflux disease (LPRD) and this was not significantly associated with post-operative Eustachian disease (p 0.061). Results of clinical tests for eustachian tube function (Valsalva manoeuvre and Toynbee manoeuvre) were difficult to appreciate by otoscopy in the ears with perforated tympanic membrane. Only 4 patients showed positive Valsalva test by otoscopy (fogging and bubbling of discharge). Toynbee test was even more difficult to appreciate. No changes were noted in the middle ear in the study population on doing Toynbee test. Tympanometric Toynbee test showed poor pre operative Eustachian tube function in 55.2% of perforated ears and was significantly associated with post-operative eustachian tube dysfunction. Size of the perforation, tympanosclerosis and severity of disease were not found to have any significant association with postoperative Eustachian tube function. 93 patients (88.6%) had intact ossicles. Only 12 patients (11.4%) had partial erosion of ossicles. 8 patients had erosion of long process of incus and 4 patients had erosion of handle of malleus. Fifty two patients (49.5%) underwent Tympanoplasty alone whereas fifty three patients (50.5%) underwent Tympanoplasty along with Cortical Mastoidectomy. 92.4% underwent type 1 tympanoplasty whereas 7.6% underwent type 2 tympanoplasty. In 81%, Temporalis fascia graft was used, whereas in 19% cartilage graft was used. On follow up, 81.9% of study population had intact graft and rest (18.1%) had graft failure. On postoperative follow up, 50.5% had A curve, 34.3% had B curve and 15.2% had C curve. Postoperatively, 50.5% had good Eustachian tube function and 49.5% had poor Eustachian tube function. Figure 2 and Table 1 displays the comparison between the statistically significant variables.

![Figure 2: Comparison of statistically significant variables based on post operative ETF](image)
Table 1. Comparison of statistically significant variables based on post operative ETF

<table>
<thead>
<tr>
<th>Comparison of statistically significant variables based on post operative ETF</th>
<th>Post operative good ETF</th>
<th>Post operative poor ETF</th>
<th>χ²</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasal allergy</td>
<td></td>
<td></td>
<td></td>
<td>5.65*</td>
</tr>
<tr>
<td>Present</td>
<td>Count: 7</td>
<td>Percent: 29.2</td>
<td>Count: 17</td>
<td>Percent: 70.8</td>
</tr>
<tr>
<td>Absent</td>
<td>Count: 46</td>
<td>Percent: 56.8</td>
<td>Count: 35</td>
<td>Percent: 43.2</td>
</tr>
<tr>
<td>Status of contralateral ear</td>
<td></td>
<td></td>
<td>30.44</td>
<td>P&lt;0.01</td>
</tr>
<tr>
<td>Normal</td>
<td>Count: 35</td>
<td>Percent: 71.4</td>
<td>Count: 14</td>
<td>Percent: 28.6</td>
</tr>
<tr>
<td>Chronic otitis media (COM) mucosal disease</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>ETD</td>
<td>Count: 17</td>
<td>Percent: 54.8</td>
<td>Count: 14</td>
<td>Percent: 45.2</td>
</tr>
<tr>
<td>Sinonasal disease</td>
<td></td>
<td></td>
<td>9.93**</td>
<td>0.002</td>
</tr>
<tr>
<td>Present</td>
<td>Count: 3</td>
<td>Percent: 16.7</td>
<td>Count: 15</td>
<td>Percent: 83.3</td>
</tr>
<tr>
<td>Absent</td>
<td>Count: 50</td>
<td>Percent: 57.5</td>
<td>Count: 37</td>
<td>Percent: 42.5</td>
</tr>
<tr>
<td>Preoperative ETF using Tympanometry</td>
<td>Good ETF</td>
<td>Count: 35</td>
<td>Percent: 74.5</td>
<td>Count: 12</td>
</tr>
<tr>
<td>Poor ETF</td>
<td>Count: 18</td>
<td>Percent: 31.0</td>
<td>Count: 40</td>
<td>Percent: 69.0</td>
</tr>
</tbody>
</table>

Association of audiological outcome after tympanoplasty with post operative eustachian tube dysfunction: The mean Air conduction -Bone conduction gap (A-B gap) closure in those with good post operative Eustachian tube function was 14.3 dB whereas it was 7.7 dB in those with poor postoperative Eustachian tube function (Figure 3).

Figure 3: Comparison of A-B gap closure based on post operative ETF

Discussion
The eustachian tube (ET) or pharyngotympanic tube is a complex organ which is a part of a system that includes the nose, palate, nasopharynx and middle ear spaces. ET dysfunction (ETD) plays an important role in etiology and pathogenesis of otitis media.[3] Eustachian tube function (ETF) testing can be used as an important tool for predicting the success rate of Tympanoplasty surgery. Both anatomical as well as physiological patency of eustachian tube plays an important role in its function. Many methods have evolved over time to evaluate eustachian tube function, but most of them are complex, invasive and are not available in many places. Even though good ETF is considered as a prerequisite for tympanoplasty, it is very difficult to assess ETF in a perforated ear even now. There are various etiological factors that can also predispose to ETD like sinonasal disease, deviated nasal septum, laryngopharyngeal reflux disease etc.

In this study, pre operatively, clinical ET patency tests like Valsalva test, Toynbee test and Tympanometric Toynbee test using GSI Tymstar were done to assess ETF in perforated tympanic membrane. Results of clinical tests for eustachian tube patency (Valsalva manoeuvre and Toynbee manoeuvre) were difficult to appreciate by otoscopy in the ears with perforated tympanic membrane. Only 4 patients showed positive valsalva test by otoscopy (fogging and bubbling of discharge). Hence a reliable statistical analysis could not be carried out. Preoperative assessment of Eustachian tube function using Tympanometry (Toynbee test) showed poor Eustachian tube function in 55.2% of study subjects and 44.8% had good Eustachian tube function in 44.8%. This was found to be significant statistically (χ²- 19.59, p value <0.01). Kanagamuthu P et al[4] in their study found that the correlation between ETF (which was done by Toynbee test in Impedance audiometry) and graft uptake showed highly significant with p value of 0.0005. Postoperatively patients were followed up to look for the results.
A good Eustachian tube function was considered as healed graft with no residual perforation and tympanometry shows A curve and eustachian tube dysfunction was considered if patient had graft failure with residual perforation or tympanometry showing B or C curve. 50.5% had good Eustachian tube function and 49.5% had poor Eustachian tube function post-operatively. According to Singh D and Sudheer C P\cite{5}(2018), 73.6% had postoperative dysfunction of Eustachian tube. 

When various etiological factors were analyzed and compared in both groups, Among the study population, 18 patients (17.1%) had history of sinonasal disease which was found to be statistically significant risk factor in the development of ETD. Among the 18 patients, 10 patients had history of chronic rhinosinusitis (CRS) with polyposis, 6 patients had chronic rhinosinusitis without polyposis and 2 had history of allergic fungal rhinosinusitis. These patients underwent functional endoscopic sinus surgery prior to the ear surgery with adequate medical treatment after surgery. Patients with obstructed deviated nasal septum had septoplasty done at least 6 week prior to ear surgery. A study by Windsor S et al\cite{6}, showed 56.7% of patients with chronic otitis media had nasal discharge and 23.3% had history of post nasal drip which was significant. Study by Stoikes et al\cite{7} also confirmed that for most CRS patients, ETD symptoms decreased in post endoscopic sinus surgery to a level comparable with a non CRS population. In our study, sinonasal disease was found to have a deleterious effect on ETF even after functional endoscopic sinus surgery

History of nasal allergy was another significant predictive factor studied. 70.8 % of study population with poor post operative eustachian tube function had history of nasal allergy. Edematous mucosa at the nasopharyngeal end of eustachian tube resulting from the nasal allergy can prolapse into lumen and cause ETD due to locking of ET. In study by M Sente et al\cite{8}, allergic rhinitis to inhalant allergens was diagnosed in 21% of subjects with eustachian tube dysfunction.

Status of contralateral ear was also significant in predicting postoperative ETD ($\chi^2$ = 30.44, p value<0.01). In the study, 46.7% had normal contralateral ear, 29.5% showed COM mucosal disease and rest 23.8% had Eustachian tube dysfunction in the contralateral ear. In a study by Damaghani and Barazin et al\cite{9}, 38% had disorder in contralateral ear (CLE) on assessing with Tympanometry, Otomicroscopy and mobility tests which showed co-relation of disease with Eustachian tube function but significance was not given. This study is in contrary to Kayhan et al\cite{10}, where both group (ear with normal contralateral and abnormal contralateral ear) had equal percentage of abnormalities. In study by S Jadia et al\cite{11}, 29% had disorder in contralateral ear which was found to be highly significant ($\chi^2$=473.15, p - 0.001).

The Air -Bone gap closure in those with good post-operative Eustachian tube function was 14.3 dB whereas it was 7.7 dB in those with poor postoperative Eustachian tube function. This showed a significant association between post-operative Eustachian tube function and hearing outcome (p value <0.01). In a study by Choi S H et al\cite{12} in 2009, post-operative AB gap closure was better (9.2 dB) in those with good Eustachian tube function. Even though hearing seemed to be improved in all groups, more improvement is noted in those with good ETF.

Other factors like sociodemographic factors, other etiological factors like laryngopharyngeal reflux disease, co morbidities, size of perforation, presence of tympanosclerotic patches, Middle ear risk index (MERI), surgical factors like whether mastoidectomy is performed or not along with tympanoplasty and types of grafting done were not found to be statistically significant in this study, hence were not risk factors for post-operative eustachian tube function.
Conclusion
The proportion of post-operative Eustachian tube dysfunction after tympanoplasty in chronic otitis media mucosal disease was 49.5%. History of sinonasal disease, nasal allergy and eustachian tube disease in contralateral ear were significant in predicting postoperative eustachian tube dysfunction. Preoperative Toynbee test using Impedence audiometry for analyzing eustachian tube function can be used as a predictor for postoperative eustachian tube dysfunction. Good audiological outcome was also associated with normal eustachian tube function. Those with good post-operative eustachian tube function had better audiological outcome in comparison to patients with poor eustachian tube function.
We suggest that sinonasal disease as well as nasal allergy should be aggressively treated before and after reconstructive ear surgeries. Preoperative eustachian tube function tests especially Toynbee test using tympanometry will be helpful in predicting postoperative eustachian tube function. Those with preoperative poor eustachian tube function should be meticulously followed up post-operatively and treated accordingly. Special attention should be paid to patients with eustachian tube dysfunction in contralateral ear and more aggressive treatment directed to improve eustachian tube function is warranted. A larger sample size could represent the burden of the disease in the community. The study was done in a tertiary care teaching hospital and hence the surgeries were performed by different surgeons. So surgical variables could be a factor in graft take up and hearing improvement, which has not been addressed in this study. We would like to conclude that preoperative assessment of eustachian tube function and control of risk factors for eustachian tube dysfunction are worthwhile endeavors towards achieving better tympanoplasty outcomes.

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Research involving human participants and/or animals:

a. Statements of human rights: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later
amendments or comparable ethical standards.

b. Statement on the welfare of animals: This chapter does not contain any studies with animals performed by any of the authors.

- **Informed consent**: Informed consent was obtained from all individual participants included in the study.

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**References**


