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ROLE OF EUSTACHIAN TUBE FUNCTION IN SUCCESS OF INTERLAY TYMPANOPLASTY

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ABSTRACT

Background: Eustachian tube function (ETF) plays a crucial role in middle ear ventilation and pressure regulation, potentially influencing outcomes of tympanoplasty. The interlay technique in Type I tympanoplasty has shown promising results in terms of graft uptake and hearing improvement. However, the impact of ETF on surgical success remains debated due to a lack of standardized assessment methods.

Objectives: To evaluate the role of Eustachian tube function in predicting graft uptake and hearing outcomes following interlay Type I tympanoplasty in patients with chronic otitis media (COM) of the tubotympanic type.

Methods: This prospective cohort study included 96 patients aged 18–47 years with inactive mucosal COM and large tympanic membrane perforations. ETF was assessed preoperatively using the Eustachian Tube Dysfunction Questionnaire-7 (ETDQ-7) and a tympanometric inflation-deflation test. All patients underwent interlay Type I tympanoplasty, and outcomes were assessed at 12 weeks postoperatively, focusing on graft uptake and hearing improvement (air-bone gap closure).

Results: ETF was normal in 33.3%, moderately impaired in 33.3%, and severely impaired in 33.3% of patients based on ETDQ-7. A significant correlation was observed between ETDQ-7 and tympanometric results ($p = 0.000225$). Graft uptake was high across all groups: 100% in normal and moderate ETF, and 96.9% in severe ETF ($p > 0.05$). Hearing improvement occurred in all groups, with mean air-bone gap closure ranging from 15.88 ± 2.71 dB to 17.34 ± 3.90 dB. Patients with normal ETF achieved better postoperative air-bone gaps (<10 dB) compared to those with impaired function ($p < 0.05$). Middle ear mucosal edema was significantly more common in patients with severe ETD ($p < 0.0001$).

Conclusion: While interlay tympanoplasty achieves high graft uptake irrespective of ETF, better hearing outcomes and healthier middle ear mucosa are associated with normal Eustachian tube function. ETF assessment using combined subjective and objective methods can aid in surgical planning and patient counselling.

Key Words: *Eustachian tube dysfunction, interlay tympanoplasty, chronic otitis media, ETDQ-7, hearing outcomes, graft uptake.*

INTRODUCTION

Otitis media is defined as inflammation of the mucoperiosteal lining of the middle ear cleft, while COM is characterized by intermittent or persistent purulent discharge through a perforated tympanic membrane, often associated with chronic mucosal inflammation or cholesteatoma formation [1].COM is broadly classified into mucosal ("tubotympanic") and squamosal ("atticoantral") types [2].

The World Health Organization (WHO) estimates that 65–330 million people globally are affected by COM, with 60% experiencing mild to moderate hearing loss. Clinically, COM is categorized into healed, inactive mucosal, active mucosal, inactive squamosal, and active squamosal types [3]. Active COM presents with persistent or recurrent otorrhea, while inactive COM shows a dry perforation.

The Eustachian tube (ET) plays a key role in middle ear ventilation, pressure regulation, and clearance of secretions [4]. ET dysfunction significantly contributes to COM development and persistence [4,5]. The continuum theory explains COM progression from ET dysfunction to effusion, tympanic membrane retraction, perforation, and cholesteatoma formation [6].

Eustachian tube function can be assessed by various methods like subjective evaluations, objective tests, and combined scoring systems, with history, otoscopy, tympanometry, nasopharyngoscopy, and the Valsalva manoeuvre providing crucial insights [5,7].

Type I tympanoplasty, typically used for inactive mucosal COM, aims to eradicate pathology, restore tympanic membrane integrity, and improve hearing. Among surgical techniques for tympanoplasty, the interlay method — where the graft is placed between the mucosal and fibrous layers — offers better preservation of middle ear space and fewer complications compared to underlay or overlay methods [8]. A randomized study done by Alam MS et al showed superior graft uptake (96%) and greater postoperative hearing improvement with the interlay technique versus the underlay technique (90%) [8].

There remains debate about the influence of ET function on tympanoplasty success; some studies report no significant association, while others stress upon its importance [9]. The lack of consensus likely reflects the absence of a definitive gold standard for ET function assessment [10]. Combining multiple ET function tests may offer better predictive value regarding surgical outcomes. The present study aims to evaluate ET function and its impact on interlay type I tympanoplasty results, with the goal of predicting postoperative outcomes like hearing improvement and disease recurrence, and optimizing surgical planning.

MATERIAL AND METHODOLOGY

Study Design and Setting

This prospective cohort study was conducted in the Department of Otorhinolaryngology of a tertiary care centre in Northern India from May 2023 to October 2024. Ethical clearance was obtained from the Institutional Ethics Committee (IEC) prior to the commencement of study. Written informed consent was taken from all participants after providing a detailed explanation regarding the purpose and procedures of the study. Patients aged between 18 and 47 years, diagnosed with tubotympanic-type chronic otitis media (CSOM) and fulfilling the inclusion criteria, were enrolled. Eligible patients presented with large central or subtotal tympanic membrane perforations, dry ears for at least one-month, no active ENT infections, and preserved cochlear function. Patients were excluded if they had atticoantral CSOM, underwent revision tympanoplasty, exhibited ossicular discontinuity or fixation, showed an air–bone gap greater than 40 dB, or had systemic illnesses, a smoking history, otitis externa, or were pregnant or lactating. Preoperative evaluation included a comprehensive clinical assessment, covering a detailed medical history, otoscopic and nasal examinations, tuning fork tests (using 256, 512, and 1024 Hz), pure tone audiometry at 500, 1000, 2000, and 4000 Hz, impedance audiometry, oto-endoscopy, X-ray mastoid (Schuller's view), ETDQ-7 scoring, and diagnostic nasal endoscopy. All patients received standardized preoperative counselling.

Assessment of Eustachian Tube Function (ETF)

ETF was evaluated preoperatively using two methods:

1) **Eustachian Tube Dysfunction Questionnaire-7 (ETDQ-7):** A validated seven-item patient-reported outcome measure. Scores were interpreted as:
- 1–2: Normal/mild dysfunction
- 3–5: Moderate dysfunction
- 6–7: Severe dysfunction

2) **Tympanometric Eustachian Tube Function Test:** Air pressure in the middle ear was artificially altered (+250 or -250 daPa) using impedance audiometry. Patients were instructed to swallow repeatedly. A step-ladder pattern returning to 0 daPa within 3–5 swallows indicated normal function; persistence of pressure beyond 5 swallows indicated dysfunction.

Surgical Procedure

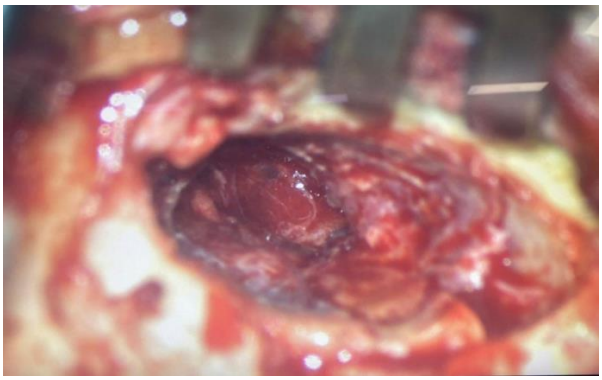
All patients underwent Type I Interlay Tympanoplasty within one week of Eustachian tube function evaluation.
Patient was administered general anaesthesia and intubated. Under all aseptic precautions, part prepared and draped. Local infiltration given in post auricular region by Plester's technique. Wilde's incision was given and temporalis fascia graft harvested. T- shaped Musculo periosteal incision given and flap elevated. Posterior meatotomy done. Margins of perforation freshened and if any myringosclerosis present, was removed. A 270-degree tympanomeatal flap elevated leaving superior part intact. The middle ear status checked and findings noted with respect to middle ear mucosa and ossicular chain. The temporalis fascia graft was placed in interlay technique, where the graft was placed between the

fibroepithelial layer and the endothelial (mucosal) layer of the TM remnant and tucked from all sides. The tympanomeatal flap was reposited.

Patients were put on regular follow-ups at 1, 2, 6, and 12 weeks. Clinical evaluation included otoscopy to assess graft status (perforation, retraction, or lateralization). Pure tone audiometry was repeated at three months to evaluate hearing outcomes, namely, Preoperative and postoperative air conduction thresholds, mean Air-Bone gap closure and overall hearing improvement.

Statistical Analysis

Statistical analysis was conducted using the Chi-square test for categorical variables and the Analysis of Variance (ANOVA) for continuous variables. A p-value of less than 0.05 was considered statistically significant, suggesting that the observed differences or associations were unlikely to have occurred by chance.



Intraoperative picture of graft placement

RESULTS

This study included 96 patients with chronic suppurative otitis media of tubotympanic type, aged between 18 to 47 years old, with mean age of 30.78 ± 8.63 years, The gender-wise distribution revealed a female predominance, with male being 27% and female being 73%.

On the basis of ETDQ7 scoring, patients were divided into three groups as: normal ET function, moderate ET dysfunction, and severe ET dysfunction, with 32 cases in each group. Simultaneously, all the cases were assessed for ET function based on tympanometry, and were divided into two groups according to ET function: Functioning ET function test (ETFT) (83.3%) and Non-functioning ETFT (16.7 %).

Eustachian tube function test based on tympanometry

Total	Functioning ET function test	Non-Functioning ET function test
96	80 (83.3%)	16 (16.7%)

1. Comparative Analysis of ETDQ-7 and Objective Eustachian Tube Function Test (ETFT) for Assessing Eustachian Tube Function

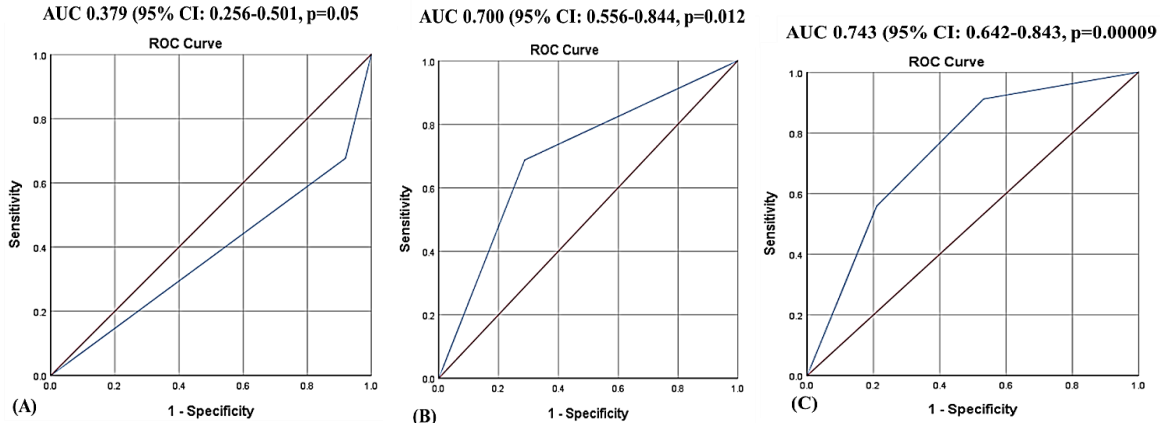
This study assessed the accuracy of ETDQ-7 and ETFT (Eustachian Tube Function Test) in evaluating Eustachian tube function across varying severity levels. ETDQ-7 scores classified patients as: 1–2 (Normal), 3–5 (Moderate ETD), and 6–7 (Severe ETD). ETFT, conducted via tympanometry, categorized function as either "Functioning" or "Non-functioning." In the normal ET group, all cases showed functioning ETFT. In the moderate ETD group, 87.5% had functioning ETFT, while 12.5% had non-functioning ETFT. The severe ETD group had the highest proportion of non-functioning ETFT (37.5%), whereas functioning ETFT was 62.5%. Overall, 83.3% of cases demonstrated functional ETFT, while 16.7% were non-functional. A significant association was found between ETDQ-7 scores and ETFT results ($p = 0.000225$), with a moderate correlation strength ($r = 0.418$).

Eustachian tube function test based on ETQ7 [Total n= 96]

Groups	ETFT		p-value#
	Functioning, no. (%)	Non-functioning, no. (%)	
Normal ETF, n=32	32 (100%)	0	**0.0002**
Moderate ETD, n=32	28 (87.5%)	4 (12.5%)	
Severe ETD, n=32	20 (62.5%)	12 (37.5%)	

#Statistical analysis computed by chi-square test; $p<0.05$=significant

Receiver Operating Characteristic (ROC) curve analysis was used to evaluate the predictive ability of ETDQ-7 and ETFT for Eustachian Tube Dysfunction (ETD). Overall, ETDQ-7 outperformed ETFT, proving more reliable for detecting ETD. However, due to its moderate specificity, additional diagnostic tests should complement ETDQ-7 in clinical decision-making.



ROC curve (A) with overall ETFT as reference; (B) ETFT-non-functioning as a reference; and (C) with ETDQ7 as reference

2. Association of Eustachian Tube dysfunction and Middle ear mucosa status

The Statistical analysis of middle ear mucosa oedema across different Eustachian tube (ET) function groups revealed varying distributions. In the normal ET group, middle ear mucosa was normal in 84.4% cases while mucosal oedema was seen in 15.6% cases. In moderate ET dysfunction, 50% cases had middle ear mucosa oedema. Whereas, in Severe ET dysfunction group, 84.4% cases had oedematous middle ear mucosa and only in 15.6% cases the mucosa was normal. A statistically significant association was observed between Eustachian tube function and the presence of mucosal oedema. Mucosal oedema being more common in patients with moderate and severe ETD compared to those with normal ET function ($p < 0.05$).

Eustachian tube function and middle ear mucosa status

Groups	Middle ear mucosa		p-value[#]
	MEM oedema, no. (%)	MEM no oedema, no. (%)	
Normal ETF, n=32	27 (84.4%)	5 (15.6%)	**p < 0.0001**
Moderate ETD, n=32	16 (50%)	16 (50%)	
Severe ETD, n=32	5 (15.6%)	27 (84.4%)	

#Statistical analysis computed by chi-square test; p<0.05=significant

3. Differences in pre- and post- operative air bone gap : Hearing Gain Analysis in Relation to Eustachian Tube Dysfunction (ETD)

Hearing improvement was assessed by comparing pre- and postoperative air-bone (AB) gaps across three groups. Preoperatively, the normal ET group had the smallest AB gap (24.50 ± 4.46 dB), increasing with ETD severity (moderate ETD: 27.97 ± 3.47 dB; severe ETD: 29.00 ± 5.91 dB). Postoperative AB gaps improved significantly in all groups: 7.69 ± 2.79 dB (normal), 12.09 ± 2.90 dB (moderate ETD), and 11.66 ± 3.53 dB (severe ETD). Hearing gain was consistent across groups, ranging from 15.88 ± 2.71 dB to 17.34 ± 3.90 dB, indicating effective surgical outcomes irrespective of ET function.

Statistical Analysis: Preoperative and postoperative AB gaps differed significantly among groups (preoperative p = 0.0006; postoperative p = 0.00000007). However, hearing gain was comparable across groups (p = 0.180). Within-group comparisons confirmed highly significant hearing improvement in all categories ($p < 0.000000001$), demonstrating the surgery's consistent efficacy across varying ETD severities.

Differences in air bone gap in pre- and post-operative cases

Chief complaints	Normal ET (n=32), %	Moderate ETD (n=32), %	Severe ETD (n=32), %	p-value[##]
Pre-operative AB gap (dB)	24.50 ± 4.46	27.97 ± 3.47	29.00 ± 5.91	0.0006
Post-operative AB gap (dB)	7.69 ± 2.79	12.09 ± 2.90	11.66 ± 3.53	0.0000007
Differences (dB)	16.81 ± 2.81	15.88 ± 2.71	17.34 ± 3.90	0.180
p-value[##]	0.000000001	0.00000000002	0.000000001	

AB: Air bone; ##Statistical analysis computed by ANOVA; p<0.05=significant (bold font)

4. **Graft Uptake and Failure Analysis**

Graft uptake success was assessed over three months. Full graft uptake was achieved in the normal ET and moderate ETD groups (100%), while the severe ETD group showed a 96.9% success rate (Table 5.4, Figure 5.4). One case (3.1%) in the severe ETD group developed graft retraction and a small perforation by three months postoperatively. This patient had a large preoperative perforation and non-functioning ETFT. Statistical analysis ($p > 0.05$) showed no significant association between ET function and graft uptake, indicating high success rates of interlay tympanoplasty (96.9–100%) regardless of ET status.

Success of graft uptake after 3 months

Groups	Graft uptake		p-value
	Success	Failure	
Normal ET (n=32), %	32 (100%)	0	0.364#
Moderate ETD (n=32), %	32 (100%)	0	
Severe ETD (n=32), %	31 (96.9%)	1 (3.1%)	

#Statistical analysis computed by chi-sq. test; p<0.05=significant

DISCUSSION

Adequate eustachian tube function is a prerequisite for the success of middle ear reconstructive surgery. Hence, assessment of ET function (ETF) is important before taking up the patient for ear surgery.

Many methods have been reported for measuring ET function. However, because no standard method is available, use of both subjective and objective test of eustachian tube dysfunction can be considered preoperatively. In our study we assessed ET function pre operatively with ETDQ7 and inflation deflation test. We found a positive relationship between preoperative ET functional measurements using a modified pressure equilibration method and ETDQ 7.

No such study has been done before which compares ETDQ7 and objective test of ETF in perforated TM.
In our study based on ETDQ-7 scores, total of 96 patients were grouped into normal ET function (1–2), moderate ETD (3–5), and severe ETD (6–7), with 32 cases each. The primary objective of our study was to assess graft uptake and hearing gain after interlay tympanoplasty in relation to ET function.

In our study, all participants in the normal ET function group had a functioning ETFT assessed by inflation – deflation test. In the moderate ETD group, 87.5% had a functioning ETFT, while 12.5% had a non-functioning ETFT. In the severe ETD group, 62.5% had a functioning ETFT, and 37.5% had a non-functioning ETFT. There was a statistically significant correlation between the ETDQ-7 scores and ETFT results ($p = 0.000225$), confirming the value of combining both subjective and objective diagnostic tools.

This finding is consistent with studies like McCoul et al. (2012), which validated ETDQ-7 as a reliable measure for capturing ETD symptoms, showing a correlation with objective tests like tympanometry and manometry [11]. Similarly, Wan et al in his study on 46 patients of COM also reported that DSVE and ETDQ-7 can provide information regarding preoperative status of eustachian tube dysfunction by measuring dynamic structural changes of the eustachian tube in combination with other diagnostic tests [12].

Ambrosio et al in his study on 130 patients of perforated TM found that a sensitivity of 80% and a specificity of 97%, a positive predictive value of 73.5% and a negative predictive value of 98% were obtained for the ETDQ7 questionnaire [13].

Choi et al. assessed Eustachian tube function in 137 patients with chronic otitis media (COM) using the inflation-deflation test and reported a higher incidence of middle ear mucosal oedema among those with poor tubal function [14]. Consistent with these findings, our study also demonstrated a progressive increase in mucosal oedema with worsening Eustachian tube function. These results further reinforce the association between the severity of Eustachian tube dysfunction and the prevalence of middle ear mucosal changes.

Postoperatively, it was found that all 80 cases (100 %) with normal Eustachian tube function had successful graft uptake. On the other hand, 16 cases had impaired Eustachian tube function and out of them, 15(93.7%) cases had successful graft take up while 1 (6.3%) case had graft failure. After applying the tests of significance, it was found that there is no significant association between Eustachian tube function and successful graft take up ($P > 0.05$), as per objective test of Eustachian tube function.

The results of present study are comparable with lot of other authors who found better graft uptake in patients with good ETF. However, this result in our study was not statistically significant.

Several authors, including Sheehy and Glasscock, Sharp, Ekvall, Bluestone, and Anderson, have reported a weak correlation between Eustachian tube function and tympanoplasty outcomes. These studies documented graft success rates exceeding 70% even among patients with poor Eustachian tube function. Holmquist also found a high rate of graft uptake in patients with impaired Eustachian tube function, reporting comparable results between those with normal and abnormal tubal function. He concluded that poor preoperative Eustachian function should not be considered a contraindication for tympanoplasty [15].

In the present study, although graft uptake did not show a statistically significant association with Eustachian tube function, hearing outcomes varied notably. A greater proportion of patients with normal Eustachian tube function achieved a reduction in air-bone gap to less than 10 dB (55/80, 68.7%) compared to those with impaired function, where only 5/16 patients (31.2%) showed similar improvement. This trend aligns with findings from other studies indicating better hearing gains in patients with normal tubal function.

Mackinnon et al noted failure of improvement in hearing in 31% of cases with severe Eustachian tube hypofunction, whereas the failure rate was only 13% in the normal function group [16]. Similarly, Biswas et al reported that tympanoplasty failure rates were significantly higher (70.84%) among patients with preoperative poor Eustachian tube function. In contrast, graft success defined as intact graft uptake without retraction or adhesions, and a postoperative air-bone gap less than 30 dB was observed in 76.31% patients with normal tubal function [17].

Previous studies on interlay tympanoplasty have reported high graft uptake rates ranging from 91.7 % to 98 %, with hearing gain typically around ~10 to 17 dB [18].

Overall, while our findings suggest that Eustachian tube function may not be a decisive factor in graft uptake, its impact on hearing outcomes remains noteworthy. However, to draw definitive conclusions, larger studies with longer follow-up durations are necessary.

CONCLUSION

This prospective study on 96 patients with chronic suppurative otitis media (tubotympanic type) assessed the role of Eustachian Tube function (ETF) in determining surgical outcomes following interlay tympanoplasty. Both subjective (ETDQ-7) and objective (inflation-deflation test) tools were used to classify ETF, and a significant correlation was observed between these modalities, reinforcing the value of combining them for preoperative evaluation.

While graft uptake rates remained consistently high (96.9–100%) across all ETF groups, regardless of dysfunction severity, hearing outcomes were notably better in patients with normal ETF. Specifically, a greater proportion of patients with normal ETF achieved a postoperative air-bone gap of less than 10 dB compared to those with impaired ETF, suggesting that tubal function plays a more critical role in functional hearing gain than in graft uptake.

Additionally, middle ear mucosal edema showed a significant association with ETF severity, further validating the importance of assessing tubal function in surgical planning. Though the impact of ETF on graft success was not statistically significant, trends in hearing improvement, mucosal changes, and comparison with existing literature highlight the clinical relevance of ETF assessment.

In conclusion, while poor Eustachian tube function should not contraindicate tympanoplasty, its influence on postoperative hearing outcomes merits careful preoperative evaluation. Further large-scale studies with long-term follow-up are warranted to refine the predictive value of ETF in middle ear surgery and guide patient selection and counselling.

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