

# Tympanoplasty Outcomes in Active and Inactive Chronic Otitis Media of Mucosal Type: A Prospective Interventional Study

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## ABSTRACT

**Introduction:** Chronic Otitis Media (COM) is a leading cause of preventable hearing loss, particularly in developing nations. It is characterised by tympanic membrane perforation and recurrent ear discharge resulting from long-standing middle ear infections. The disease is classified into inactive (dry) and active (wet) types based on the absence or presence of mucopurulent discharge.

**Aim:** To compare the success rate of graft uptake and hearing improvement in tympanoplasty performed in patients with inactive (dry) and active (wet) mucosal COM.

**Materials and Methods:** This prospective interventional study was conducted at FH Medical College and Hospital, Agra, Uttar Pradesh, India over a period of 1.5 years. A total of 110 patients diagnosed with mucosal COM were divided into two groups: inactive and active. Preoperative and postoperative assessments, including Pure Tone Audiometry (PTA), were

performed to evaluate hearing improvement, and clinical examination was used to assess graft uptake. The follow-up period was three months post-surgery. The two groups were compared for graft uptake and hearing improvement using an Independent samples t-test.

**Results:** The graft uptake rate was 87.5% in the inactive group and 84.78% in the active group. Hearing improvement, measured by reduction in PTA thresholds, was slightly better in the inactive group (12.19 dB improvement) compared to the active group (11.09 dB improvement). However, the difference was not statistically significant.

**Conclusion:** Tympanoplasty is an effective surgical intervention for mucosal COM, with high success rates in both inactive and active cases. Although inactive ears demonstrated marginally better graft uptake and hearing improvement, the presence of active discharge at the time of surgery did not significantly affect the overall surgical outcome.

**Keywords:** Dry ear, Ear discharge, Hearing loss, Myringoplasty, Wet ear

## INTRODUCTION

The COM is a leading cause of preventable hearing loss, particularly in developing nations. It is characterised by tympanic membrane perforation and recurrent ear discharge resulting from long-standing middle ear infections [1]. Long-standing COM may also result in ossicular erosion and aural polyp formation [2]. COM is of two types: mucosal and squamous. Tympanoplasty is performed in the mucosal type to repair the perforation, eradicate disease from the middle ear, and improve hearing [3]. The disease is further classified into inactive (dry) and active (wet) types based on the absence or presence of mucopurulent discharge.

The outcome of tympanoplasty depends on the size and location of the perforation, eustachian tube function, and whether the ear is dry or wet before surgery. Otolologists often face a dilemma regarding operating on wet ears, as literature traditionally suggests better outcomes in dry ears. However, recent studies indicate that with appropriate preoperative and postoperative antibiotic coverage, surgical outcomes in dry and wet ears are comparable. One study even reported better graft uptake rates in wet ears due to increased vascularity [4].

In India, patients with COM often seek medical attention only when ear discharge is present, requiring multiple visits to achieve a dry ear prior to surgery [5]. As the disease commonly affects individuals from lower socio-economic backgrounds, repeated visits impose financial strain and loss of workdays, leading many patients to discontinue treatment. Therefore, this study aims to evaluate whether active discharge significantly influences tympanoplasty outcomes. The objectives of the study were to compare the graft uptake rate in inactive and active COM and also to compare hearing improvement in inactive and active COM.

## MATERIALS AND METHODS

This prospective interventional study was conducted in the Department of Otorhinolaryngology at FH Medical College and Hospital, Agra, Uttar Pradesh, India over a period of 1.5 years (September 2022 – March 2024). Ethical approval was obtained from the Institutional Ethics Committee (Ref. No. FHMC/IEC/R/Cell/2022/19), and written informed consent was secured from all participants. All procedures involving human participants were conducted in accordance with institutional and national research ethics standards, as well as the 1964 Helsinki Declaration and its subsequent amendments.

### Inclusion criteria:

- Age between 18 and 60 years;
- No evidence of active infection in the nose or throat;
- Central perforation of the tympanic membrane;
- Conductive hearing loss without sensorineural component;
- Patent eustachian tube.

### Exclusion criteria:

- Marginal or attic perforation;
- Evidence of cholesteatoma, squamous epithelium in the middle ear, polyps, or ossicular erosion;
- Only hearing ear;
- Sensorineural hearing loss;
- Revision tympanoplasty cases;
- Complicated otitis media;
- Pregnant or lactating women;
- Patients with underlying conditions such as diabetes, hypertension, bronchial asthma, tuberculosis, or immunocompromised states.

**Sample size:** The average prevalence of chronic suppurative otitis media in India is 5.2% [6]. Using a 95% confidence level and 5% margin of error, the calculated sample size was 76. A total of 118 patients were initially enrolled; six were lost to follow-up and two were excluded due to severe illness. Thus, data from 110 patients were analysed. Patients were categorised into inactive and active COM groups based on the absence or presence of ear discharge.

Criteria for dry and wet ear [7]:

#### Inactive COM (Dry ear):

- Ear dry for at least six weeks;
- Tympanic membrane remnant of normal colour with healthy middle ear mucosa.

#### Active COM (Wet ear):

- Congestion of tympanic membrane remnant;
- Congestion of middle ear mucosa;
- Presence of mucoid discharge, polypoidal changes, or mucosal hypertrophy.

**Surgical procedure:** All patients underwent Type I tympanoplasty using the underlay technique with temporalis fascia graft. Standard postoperative care included antibiotics, strict ear hygiene, and follow-up evaluation at three months.

### Outcome Measures

- Primary outcome:** Graft uptake success rate;
- Secondary outcome:** Hearing improvement assessed by PTA.

Successful graft uptake was defined as complete healing of the tympanic membrane with an intact, well-epithelialised graft securely incorporated into the remnant tympanic membrane, without residual perforation or lateralisation, as assessed by postoperative otoscopic examination (typically at 6-12 weeks) [8].

### STATISTICAL ANALYSIS

Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) software (SPSS Inc., Chicago, IL, USA), version 26.0 for Windows. A paired t-test was used to compare the status of the tympanic membrane before and after surgery within each group. To compare graft uptake and hearing improvement between the two groups, an independent samples t-test was applied. A p-value $\leq$ 0.01 was considered as statistically significant.

### RESULTS

The study included 110 patients, of whom 61 (55.45%) were female and 49 (44.55%) were male (male:female=1:1.24). Dry ears were observed in 64 (58.18%) patients and wet ears in 46 (41.82%) patients. The majority of patients, 42 (38.18%), were aged 31-40 years, followed by 36 (32.73%) aged 21-30 years. The mean age was 31.46 years, with a median of 31 years and a Standard Deviation (SD) of 9.648 [Table/Fig-1].

Age group (years)	Male	Female	n (%)
18-20	5	10	15 (13.64)
21-30	15	21	36 (32.73)
31-40	18	24	42 (38.18)
41-50	7	4	11 (10)
51-60	4	2	6 (5.45)
Total	49	61	110

[Table/Fig-1]: Age and gender distribution.

Most patients had medium-sized perforations, seen in 52 (47.27%) cases, including 32 inactive and 20 active cases. Large perforations were present in 20 inactive and 18 active cases, while small perforations were noted in 12 inactive and 8 active cases. Bilateral

disease was observed in 38 patients: 21 in the inactive group and 17 in the active group [Table/Fig-2].

Disease status	Unilateral n (%)	Bilateral n (%)	Total n (%)
Inactive disease	43 (67.19)	21 (32.81)	64 (100)
Active disease	29 (63.04)	17 (36.96)	46 (100)
Total	72 (65.45)	38 (34.55)	110 (100)

[Table/Fig-2]: Distribution of unilateral and bilateral disease.

Preoperative hearing assessment revealed that most patients, 90 (81.8%), had moderate conductive hearing loss. In the inactive group, 52 (81.25%) patients had moderate hearing loss, while in the active group, 38 (82.6%) patients had moderate conductive hearing loss in the range of 41-55 dB. Twenty (18.18%) patients had mild conductive hearing loss (26-40 dB), including 12 (18.75%) in the inactive group and 8 (17.39%) in the active group [Table/Fig-3].

S.No.	Hearing loss (dB)	No. of inactive cases	No. of active cases	Total
1	<26	0	0	0
2	26-40	12 (18.75)	08 (17.39)	20 (18.18)
3	41-55	52 (81.25)	38 (82.61)	90 (81.82)
Total		64 (100)	46 (100)	110 (100)

[Table/Fig-3]: Preoperative hearing assessment.

Of the 110 patients, 96 (87.27%) had an air-bone gap greater than 25 dB at presentation. Fourteen (12.72%) patients had an air-bone gap of less than 25 dB; among them, 10 had inactive disease and four had active disease [Table/Fig-4]. The mean preoperative hearing threshold was  $44.39 \pm 6.5$  dB in the inactive group and  $44.19 \pm 6.85$  dB in the active group.

AB gap status	Inactive disease	Active disease	Total
Preoperative AB gap $\leq$ 25 dB	10 (15.62)	04 (8.6)	14 (12.73)
Preoperative AB gap >25 dB	54 (84.37)	42 (91.30)	96 (87.27)
Mean preoperative hearing threshold (dB)	$44.39 \pm 6.5$	$44.19 \pm 6.85$	–
Postoperative AB gap $\leq$ 25 dB (after 12 weeks)	45 (70.31)	33 (71.73)	78 (70.90)
Postoperative AB gap >25 dB (after 12 weeks)	19 (29.68)	13 (28.26)	32 (29.09)
Mean postoperative hearing threshold (dB)	$32.20 \pm 9.6$	$33.1 \pm 9.07$	–

[Table/Fig-4]: Comparison of preoperative and postoperative air-bone gap.

Postoperative hearing assessment at 12 weeks showed that 17 (15.45%) patients had normal hearing (nine inactive, eight active), 68 (61.82%) had mild hearing loss (39 inactive, 30 active), and 25 (22.73%) had moderate hearing loss (16 inactive, nine active) [Table/Fig-5].

S.No.	Hearing Loss (dB)	No. of inactive cases	No. of active cases	Total
1	<26	9 (14.06)	8 (17.39)	17 (15.45)
2	26-40	39 (60.94)	29 (63.04)	68 (61.82)
3	41-55	16 (25)	9 (19.56)	25 (22.73)
Total		64 (100)	46 (100)	110 (100)

[Table/Fig-5]: Postoperative hearing assessment.

After 12 weeks, 78 (70.90%) patients had an air-bone gap of less than 25 dB, including 45 (70.31%) from the inactive group and 33 (71.73%) from the active group. A total of 32 (29.09%) patients had an air-bone gap greater than 25 dB, with 19 (29.68%) in the inactive group and 13 (28.26%) in the active group [Table/Fig-4].

The mean hearing threshold improvement at 12 weeks postoperatively was 12.19 dB in the inactive group, which was statistically significant (p-value $<0.001$ ), and 11.09 dB in the active group, which was also statistically significant (p-value $<0.001$ ).

However, the difference in mean hearing improvement between the two groups was not statistically significant ( $p$ -value=0.4866) [Table/Fig-6].

Type of ear disease	Preoperative mean hearing threshold (dB)	Postoperative mean hearing threshold (dB)	Improvement in mean hearing threshold (dB)	p-value
Inactive disease	44.39±6.5	32.20±9.6	12.19	0.4866
Active disease	44.19±6.85	33.1±9.07	11.09	

**[Table/Fig-6]:** Improvement in hearing thresholds of inactive and active disease.

Postoperative graft uptake was assessed at 12 weeks. A total of 95 (86.36%) patients demonstrated intact grafts, including 56 (87.5%) in the inactive group and 39 (84.78%) in the active group [Table/Fig-7]. Although graft uptake was slightly higher in the inactive group, the difference was not statistically significant ( $p$ -value=0.68).

Type of ear disease	No. of patients	No of patients with successful graft uptake	Percentage success	p-value
Inactive disease	64	56	87.5%	0.68
Active disease	46	39	84.78%	
Total	110	95	86.36%	

**[Table/Fig-7]:** Status of graft uptake.

Among the 15 patients with graft failure, six had dry ears and nine had persistent otorrhoea; of these, two belonged to the inactive group and seven to the active group. Bilateral disease was observed in nine patients with graft failure. Regarding perforation size, nine patients had large perforations and six had medium-sized perforations. Two patients in the active group also developed stitch abscesses.

## DISCUSSION

The COM is characterised by persistent inflammation of the mucoperiosteal lining of the middle ear cleft, resulting in recurrent ear discharge through tympanic membrane perforation. Based on pathology and perforation type, COM is classified into mucosal and squamous forms. It represents a major cause of hearing impairment, particularly in developing countries due to socio-economic and nutritional factors [9]. Tympanoplasty comprises five types of procedures, with Type I aimed exclusively at repairing the tympanic membrane [10]. Surgery remains the mainstay of treatment for COM, with the objectives of eradicating disease, restoring hearing, and preventing recurrence. In mucosal COM, tympanoplasty is the preferred surgical approach to re-establish the middle ear's sound-conducting mechanism. Although tympanic membrane repair generally yields favourable results, outcomes may vary due to infection, eustachian tube dysfunction, and technical factors [11].

This study aimed to evaluate the effect of disease status (inactive versus active) on tympanoplasty outcomes. A total of 110 patients were followed over 18 months. The male-to-female ratio was 1:1.24, comparable to the ratio of 1:1.21 reported by Lin YC et al., [12]. The largest proportion of patients (38.18%) belonged to the 31-40-year age group, followed by the 21-30-year group (32.73%). The mean age was 31.46 years, with a median of 31 years and an SD of 9.648. These findings differ from those of Nagle SK et al., and Singh BJ et al., where the majority of patients were in the 21-30-year age group [13,14]. In a study conducted by Raj A and Vedit T, it was found that there was no increased risk of graft failure, and myringoplasty in wet ears was as successful as in dry ears [15]. The present study similarly demonstrated no significant difference in graft uptake rates between inactive and active disease.

Adkins WY et al., reported no association between patient age or disease duration and tympanoplasty outcomes; however, bilateral disease was linked to poorer results [16]. In the present study, nine out of 15 graft failures occurred in patients with bilateral disease.

Bilateral involvement is considered a poor prognostic factor, presumably because otitis media in these patients tends to have a more severe or prolonged course.

Emir H et al., observed graft uptake rates of 88.6% in dry ears and 88% in wet ears [17], which are comparable to the present study's rates of 87.5% in inactive disease and 84.78% in active mucosal disease. They also reported significant hearing improvement in 77.7% of dry ears and 78.4% of discharging ears. In the present study, significant hearing improvement was noted in 70.31% of patients in the inactive group and 71.73% in the active group. Although both studies showed slightly better improvement in active disease, the differences were not statistically significant. Conversely, Pothala H et al., found greater hearing improvement in dry ears compared to wet ears (87.14% vs. 77.14%) [18].

Vertiainen E et al., studied 404 myringoplasty cases and reported a success rate of 88% [19]. In another analysis of 417 cases, Vertiainen E et al., identified 44 failures and found graft necrosis and anterior blunting to be the most common causes. They also reported higher failure rates in large perforations, while grafting techniques did not significantly influence uptake [20]. In the present study, among the 15 failures, nine involved large perforations and six involved medium-sized perforations.

Overall, graft success in the present study was 87.5% in inactive disease and 84.78% in active disease. A comparison of findings with previous studies is summarised in [Table/Fig-8] [17,21,22]. Raj A and Vedit T, observed an 84% success rate in wet ear tympanoplasty [15]. Interestingly, Vijayendra H et al., found higher graft uptake in wet ears, attributing this to reduced vascularity in completely dry tympanic membranes [4].

S. No.	Study	Place of study	Graft success in dry/inactive ear	Graft success in wet/ active ear
1	Present study, 2026	North India	87.5%	84.78%
2	Emir H et al., 2007 [17]	Ankara, Turkey	88%	88.6%
3	Glasscock ME et al., 1982 [21]	United States	93.15%	92.7%
4	Sarker MZ et al., 2011 [22]	Bangladesh	89.36%	53.85%

**[Table/Fig-8]:** Comparison of the results with previous studies in the literature [17,21,22].

## Limitation(s)

This study had several limitations. It was a single-centre study involving a local population, and the follow-up period was limited to three months. With longer follow-up, inactive and active disease may show different rates of tympanic membrane reperforation, potentially altering final outcomes. Therefore, multicentre studies with larger sample sizes and extended follow-up periods are recommended.

## CONCLUSION(S)

Tympanoplasty remains a reliable treatment for mucosal COM. Although inactive ears demonstrated slightly better outcomes, tympanoplasty in active ears was equally effective when performed under appropriate infection control measures. These findings indicate that the presence of mild discharge should not be considered a contraindication to surgery, enabling earlier intervention and improved patient outcomes.

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