Surgical Outcome in Patients Undergoing Tympanoplasty Alone for Active Chronic Otitis Media Mucosal Type in Hilly Area

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Abstract

Introduction Chronic otitis media (COM) is a common problem affecting 65 to 330 million population worldwide with 50% patients suffering from hearing impairment. In active COM, the usual clinical practice is to wait for the ear to become dry and to consider tympanoplasty with/without cortical mastoidectomy. If cortical mastoidectomy can be avoided without compromising the outcomes, it is desirable. Various prognostic factors have been studied; however, the effect of altitude on the outcome of tympanoplasty has not been commonly studied. High-altitude areas can have poor connectivity and can result in middle ear pressure changes when the patients commute from low-altitude areas.

Aim The aim of this article was to assess the surgical outcome in patients undergoing tympanoplasty for active COM mucosal type in comparison to inactive COM mucosal type in a hilly area located at an altitude of 4,757 ft (1,450 m).

Objective This article compared the success rate and audiometric improvement in patients undergoing tympanoplasty for active COM mucosal type and inactive COM mucosal type.

Materials and Methods This prospective cohort study included 24 patients with 12 patients each in active and inactive groups. At 3 months follow-up, there was significant improvement in all the air conduction threshold frequencies and air bone gap in both the groups.

Conclusion The success rate for our tympanoplasties for active and inactive COM performed in a hilly area was 92% and it was comparable to those reported from other centers. Altitude may not negatively affect the outcome of tympanoplasty and that the active ear COM can have similar success rate as inactive COM tympanoplasty.

Keywords
- altitude
- audiometry
- hearing loss
- otitis media
- otorhinolaryngology
- surgical outcome

Introduction

Chronic otitis media (COM) is a common problem affecting 65 to 330 million population worldwide with 50% of patients suffering from hearing impairment. Around 28,000 deaths per year are due to the complications of COM according to the World Health Organisation (WHO). Active COM mucosal type has permanent defect of the pars tensa with an inflamed middle ear and mastoid mucosa that produces mucopus.[1]

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Inactive COM mucosal type has permanent defect of the pars tensa without any inflammation or discharge in the middle ear and mastoid mucosa.

Persistent or repeated bouts of infection in active COM mucosal type have increased risk of complications like progressive ossicular destruction and can potentially cause damage to the inner ear due to toxins. Hence, early and effective treatment of active COM mucosal type is necessary. Medical management is the initial line of treatment to control inflammation and topical antibiotic and or systemic antibiotic is the most commonly used regimen.[1,2] Definitive management is by surgery and the surgery can be tympanoplasty alone or tympanoplasty with cortical mastoidectomy. It is believed that disturbance in ventilation of mastoid at the time of initial tympanoplasty plays a major role in active COM mucosal type and hence cortical mastoidectomy is considered as a necessary adjuvant surgical procedure by otolaryngologists.[3,4]

The usual clinical practice is to wait for the ear to become dry and to consider cortical mastoidectomy with tympanoplasty in patients with active COM mucosal type. If cortical mastoidectomy can be avoided in patients without compromising the outcomes, it will be welcomed by the otolaryngologists and patients as it is more extensive surgery than tympanoplasty, more invasive, and is not without additional risk of complications.[5] Avoiding cortical mastoidectomy reduces the surgical time and maintains the normal anatomy and physiology of the mastoid air cell system. With the advent of endoscopic ear surgeries, the middle ear maybe examined in detail and any blockage in aditus and attic, eustachian tube, and ventilatory pathways can be removed endoscopically without the need for cortical mastoidectomy.

In many centers, cortical mastoidectomy with tympanoplasty is still considered for active COM mucosal type that is refractory to medical management. Previous studies have been conducted on inactive COM mucosal type comparing tympanoplasty with or without cortical mastoidectomy.[6,7]

Various prognostic factors have been studied that may affect the outcome of tympanoplasty for COM mucosal type. The effect of altitude on outcome of tympanoplasty has not been commonly studied. Our study considers altitude in the outcome evaluation and compares the success rates with other studies reported from elsewhere. Our center is in a hilly area at an altitude of 4,757 ft (1,450 m).[8]

Aim

The aim of this article was to assess the surgical outcome in patients undergoing tympanoplasty for active COM mucosal type in comparison to inactive COM mucosal type in hilly area.

Objective

1. To compare the success rate in patients undergoing tympanoplasty for active COM mucosal type and inactive COM mucosal type.
2. To compare the audiometric improvement in patients undergoing tympanoplasty for active COM mucosal type and inactive COM mucosal type.

Materials and Methods

This prospective cohort study was conducted in the department of otorhinolaryngology in our institute from May 2019 to May 2021 after obtaining Institutional Ethics Committee approval. It included 24 patients who underwent tympanoplasty of which 12 had active COM and 12 had inactive COM.

Inclusion Criteria

1. Patients of both the genders above or equal to 15 years of age with COM mucosal type with conductive hearing loss (HL).
2. Patients willing to get operated and participate in the study.

Exclusion Criteria

1. Patients who were operated previously on the same side.
2. Patients with uncontrolled diabetes mellitus, hypertension, and tuberculosis.
3. Patients with sensory neural HL on same side.
4. Patients with untreated sinusitis, chronic adenotonsillitis, and symptomatic deviated nasal septum.
5. Patients with COM squamous type (atticoantral type) or any other middle ear disorder.

Withdrawal Criteria

Patients withdrawing consent.

Patients in "AGroup" were defined as those with permanent perforation in pars tensa and minimal to profuse ear discharge. They were given a trial of topical ciprofloxacin 0.3% w/v ear drops for at least 1 week and/or oral amoxicillin + clavulanate (according to body weight) for 7 days along with systemic antihistamine (levocetirizine 5 mg once a day). Those patients' middle ear mucosa continued to be inflamed with or without ear discharge even after repeated courses of antibiotics.

Patients in "IAGroup" were defined as those with permanent perforation of pars tensa without any evidence of active inflammation or ear discharge in the preceding 12 weeks before surgery.

AGroup patients were reassessed clinically and counselled regarding the need for surgery to render the ear inactive and to treat the HL. Patients who were willing to be operated were included in the study after informed consent. AGroup and IAGroup patients underwent pure tone audiometry (PTA) and speech audiometry, along with routine blood investigations required for surgery. They underwent tympanoplasty under local anesthesia. Endoscopic tympanoplasty was done in patients in whom the canal was wide by giving Rosen's incision. Postaural approach was done in patients in whom the canal was narrow by giving William Wilde incision. Tympanomeatal flap was elevated and middle ear cavity was entered. Temporalis fascia graft was harvested and grafted by underlay technique.

All patients received the routine postoperative care like systemic antibiotic injection, cleaning, and dressing of wound as and when required. Patients were usually discharged on second day and suture removal was done on seventh postoperative day.

Preoperatively patient's PTA, air bone gap (ABG), size of perforation, and word recognition score (WRS) were noted. The following findings were noted intraoperatively—size of perforation, presence of discharge, middle ear mucosa status, and ossicular status. Postoperatively at 6 weeks and at 3 months patient's PTA, graft uptake, and WRS were assessed. Patients were also monitored for any complications.

The PTA average was calculated as the average of air conduction (AC) thresholds at 500, 1,000, and 2,000 Hz. WRS was calculated by delivering a minimum of 50 words which the patient can comprehend at a presentation level of 40 dB sensory level and calculating the percentage of words which the patient can repeat correctly. The calculated PTA average was plotted along Y-axis and the WRS score was plotted along X-axis and the Scattergram was created as per the American Academy of Otolaryngology-Head and Neck Surgery (AAOHNS) recommendation.[9] The size of the perforation was classified as small, medium, and large when one, two, and more than two quadrants of pars tensa were involved, respectively. The degree of HL was classified based on Clark's classification.[10] Between −10 and 15 dB was considered as normal. Slight, mild, moderate, moderately severe, severe, and profound HLs were 16 to 25 dB HL, 26 to 40 dB HL, 41 to 55 dB HL, 56 to 70 dB HL,71 to 90 dB HL, and more than 90 dB HL, respectively. Graft uptake was considered satisfactory if there was no residual perforation and with graft in normal position at the end of 3 months follow-up. The data was collected in Microsoft Excel 2017 and data analysis was done using IBM PASW statistics v19.0 (SPSS version 19.0). The effect of variables like tympanic membrane inflammation (TM), middle ear mucosal oedema, congestion, discharge, otomycosis in both AGroup and IAGroup were analyzed using Fischer's exact test. The improvement in patients' AC average and ABG average at 3 months from the preoperative AC Average and ABG average was compared using paired *t*-test. The improvement in PTA, AC average, and ABG at 3 months between AGroup and IAGroup was compared by unpaired *t*-test. All the statistical tests were considered statistically significant at a *p*-value of less than or equal to 0.05.

Results

A total of 24 patients were included in the study with 12 in AGroup and 12 in IAGroup.

AGroup: Seven patients were male (58%). The mean age was 35 ± 12 years with minimum age being 15 years and maximum age being 55 years. The minimum and maximum duration of disease was 6 months and 10 years, respectively, with mean duration being 4 years. Bilateral disease was present in 6 (50%) patients. History of ear discharge and HL were the common presentations seen in all 12 patients of AGroup. Tinnitus was seen in three (25%) patients. Six (50%) patients had moderately severe HL. Medium-sized central perforation was seen in nine (75%) AGroup patients. Intraoperatively TM inflammation was seen in two (17%) AGroup patients. Middle ear mucosal edema was seen in 12 (100%) and middle ear discharge in 9 (75%) patients of AGroup. Eleven (92%) patients had all three ossicles intact and mobile. One patient (8%) did not have handle of malleus in AGroup. Ten patients (84%) in AGroup underwent type I endoscopic tympanoplasty, one patient (8%) underwent type II endoscopic tympanoplasty, and one patient (8%) underwent microscopic postaural type I tympanoplasty owing to narrow ear canal. Temporalis fascia graft was used in all. At 6 weeks following surgery, one patient (8%) had granulation in posterior external auditory canal. At 3 months follow-up period, 11 (92%) patients had intact graft in normal position. One (8%) patient in AGroup had lateralization of graft with worsened hearing. It was considered as failure of surgery.

IAGroup: Five patients were male (42%). The mean age was 25 ± 8 years with minimum age being 15 years and maximum age being 38 years. The minimum and maximum duration of disease was 2 months and 10 years, respectively, with mean duration being 2 years. Bilateral disease was present in three (25%) patients. History of HL was the commonest presentation seen in eleven (92%) patients. Past history of ear discharge was seen in nine (75%) patients in IAGroup. Tinnitus was seen in three (25%) patients in IAGroup. Vertigo was not seen in any patient of AGroup or IAGroup. Six (50%) IAGroup patients had mild HL. Intraoperatively large central perforation was seen in eight (67%) IAGroup patients. All 12 patients (100%) in IAGroup had all three ossicles. Six patients (50%) underwent type I endoscopic tympanoplasty in IAGroup. One patient (8%) underwent microscopic per meatal type I tympanoplasty. Five patients (42%) underwent microscopic postaural type I tympanoplasty owing to narrow ear canal. Temporalis fascia graft was used. At 6 weeks following surgery, one patient (8%) in IAGroup had granular myringitis. At 3 months follow-up, one (8%) patient had residual perforation and 11 (92%) patients had intact graft in normal position (►**Figs. 1** and **2**).

In both the groups, the effects of age, gender, duration of disease, size of perforation, type of surgery, and approach and in AGroup the effects of TM margin inflammation, middle ear mucosa status, congestion, discharge, and otomycosis on graft uptake were studied using Fischer's exact test. There was no significant association between the factors studied and graft uptake (►**Table 1**).

There was significant improvement in AC thresholds in both groups following surgery. There was no statistically significant difference noted between the audiological outcomes of AGroup and IAGroups. The success rate in both the groups was 92% (►**Tables 2** and **3**).

Discussion

Traditionally tympanoplasty was performed for COM mucosal type after rendering the ear inactive. Presence of infection was considered as a poor prognostic factor for good surgical outcome.[1] However, recent studies that are emerging support the idea of tympanoplasty even in cases of active COM mucosal type. Traditionally, cortical mastoidectomy was combined with tympanoplasty for active COM mucosal type. Due to conflicting results from previous studies, many surgeons in different centers are skeptical to operate on active COM mucosal type. Even if surgery is planned, the extent of

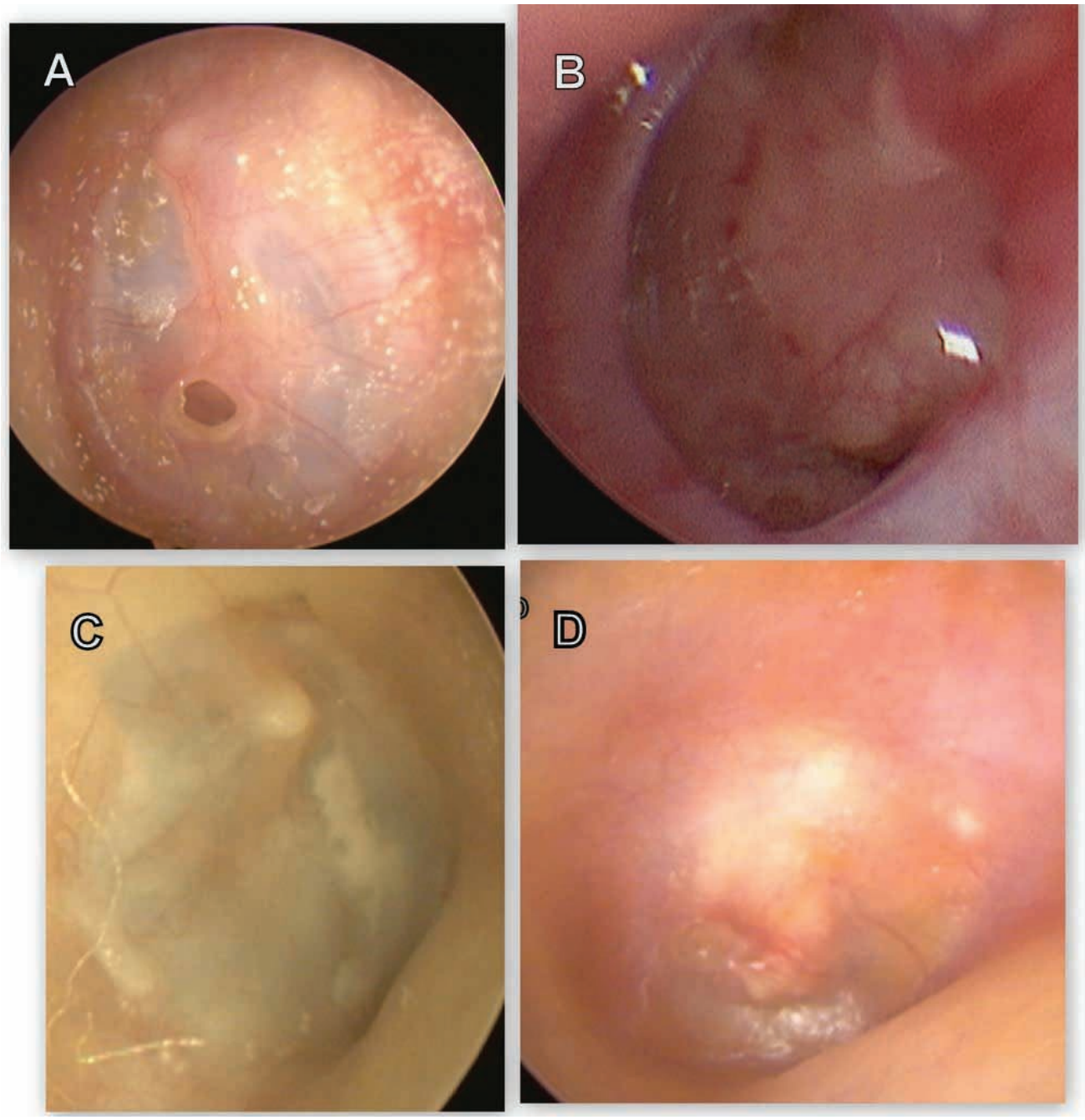

Fig. 1 (**A**) Inactive chronic otitis media (COM) left side. (**B**) Active COM right side with inflamed tympanic membrane and moist middle ear mucosa. Post-tympanoplasty otoendoscopy images at 3 months follow up for (C) inactive COM mucosal type and (D) active COM mucosal type.

surgery is debatable, that is, tympanoplasty alone or tympanoplasty with cortical mastoidectomy.[4]

In our study, all patients were above 15 years of age. Our success rate was 92% in both the groups that is comparable to other studies.[11] In our study, patient's age, gender, duration of disease, size of perforation did not affect the surgical outcome. In a study by Naderpour et al, the size of perforation did not have any effect on outcome, similar to our study.[11] However, in a meta-analysis the size of perforation above 50% had lower success rate compared to smaller perforation.[12] The difference in observation can be attributed to the small sample size in our study.

Signs of middle ear inflammation like TM congestion, middle ear mucosa, and edema/congestion did not significantly affect the outcome in our study. Similar observation was noted by Shankar et al in which remnant TM was biopsied during tympanoplasty and the vascularity was studied. It did not significantly alter the outcome.[13]

In our study, the presence of discharge did not significantly affect the outcome. Some surgeons advocate grading of discharge in active COM patients. It can help the surgeon to assess the severity of the disease, the effectiveness of treatment, in patient counselling. The grading of ear discharge along with other factors like presence of perforation,

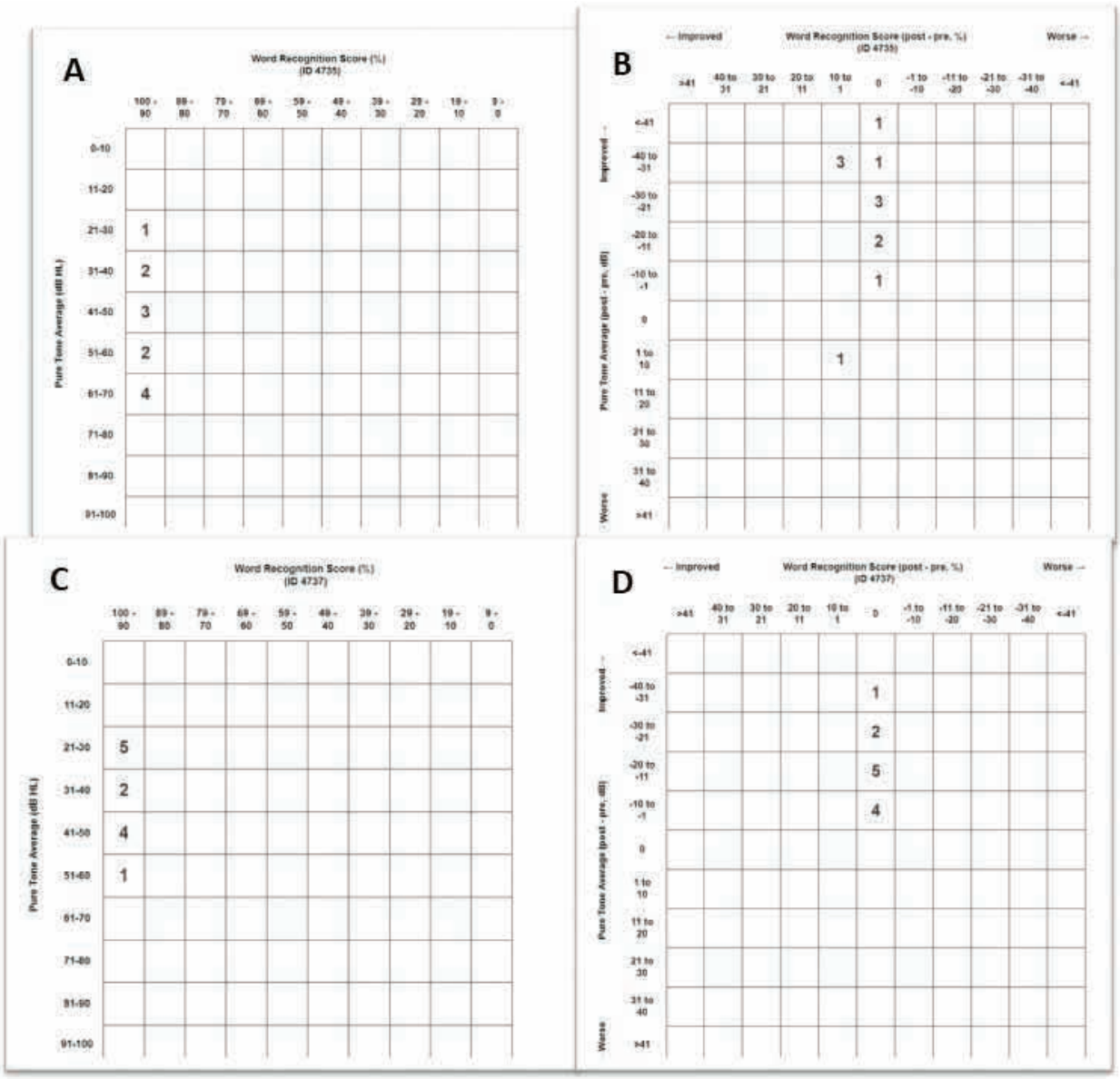

Fig. 2 Scattergrams of AGroup (**A** and **B**) and IAGroup (**C** and **D**) created by plotting word recognition score (WRS) along X-axis and pure tone audiometry (PTA) along Y-axis. (**A**) Pretreatment chart shows the distribution in number of patients with various degrees of hearing loss. All patients had WRS of 90 to 100%. (**B**) Post-treatment change chart shows the degrees of improvement in PTA with 11 patients showing improvement and one patient showing worsening of PTA. (**C**) Pre-treatment chart shows the distribution in number of patients with various degrees of hearing loss. All patients had WRS of 90 to 100%. (**D**) Post-treatment change chart shows the degrees of improvement in PTA with all 12 patients showing improvement.

cholesteatoma, granulation, ossicular statu, previous surgery, and smoking constitutes middle ear risk index (MERI). Shishegar et al found that patients with low MERI score needed only tympanoplasties and had higher success rate compared to those with high MERI score who needed tympanoplasties with mastoidectomy.[14]

In our study, the factors related to surgery like microscopic/endoscopic; permeatal/postaural did not significantly affect the outcome. In our study, temporalis fascia graft was used in all patients. Salviz et al recommended cartilage perichondrium flaps in high-risk patients like children, adenoid or septal pathology, and contralateral ear disease.[15] Similar finding was reported by Tan et al in their study.[12] None in our study had any risk described and hence only temporalis fascia graft was used.

There was significant improvement in all the AC threshold frequencies tested in both the AGroup and IAGroup at 3 months follow-up period. There was also significant reduction in ABG at 3 months post-surgery compared to the preoperative ABG. The audiological outcome was compared between the AGroup and IAGroup and there was no statistically significant difference noted between the two groups thus emphasizing that active COM may not negatively affect the outcome of tympanoplasty in our study population. Similar finding was noted by

Table 1 Characteristics studied in AGroup and IAGroup

Characteristic	AGroup	IAGroup	Test	*p*-Value
TM margin inflammation				
Present	2	0	Fischer's exact test	0.478
Absent	10	12		
Middle ear mucosal oedema				
Present	12	0	Chi-squared test	0.000[a]
Absent	0	12		
Congestion				
Present	1	0	Fischer's exact	1.000
Absent	11	12		
Discharge				
Present	5	0	Fischer's exact	0.037[a]
Absent	7	12		
Otomycosis				
Present	1	0	Fischer's exact	1.000
Absent	11	12		
Graft uptake				
Success	11	11	Fischer's exact	1.000
Failure	1	1		

Abbreviation: TM, tympanic membrane.
[a]Significant ***p*-Value** < 0.05

Table 2 Audiological improvement in AGroup and IAGroup

Group	Hearing thresholds	Preoperative mean ± SD	Postoperative mean ± SD	Difference in mean ± SD	*p*-Value
AGroup	Air conduction	51.33 ± 12.4	26.00 ± 15.33	25.3 ± 15.1	< 0.01
	Air bone gap	37.75 ± 9.08	15.67 ± 12.55	22.1 ± 14.7	< 0.01
IAGroup	Air conduction	38.33 ± 10.26	21.00 ± 3.69	17.3 ± 8.4	< 0.01
	Air bone gap	26.17 ± 6.87	11.75 ± 3.59	14.41 ± 6.5	< 0.01

Abbreviation: SD, standard deviation.[a]Paired *t*-test

Table 3 Comparison of postoperative audiological outcome at 3 months between AGroup and IAGroup

Hearing thresholds	AGroup mean ± SD	IAGroup mean ± SD	Difference	*p*-Value
Post PTA 3 months (dB)	25.4 ± 14.5	20.8 ± 4	4.6	0.294
Post AC average 3 months (dB)	26 ± 15.3	21 ± 3.7	5.0	0.284
Post ABG 3 months (dB)	15.7 ± 12.6	11.8 ± 3.6	3.9	0.310

Abbreviations: ABG, air bone gap; AC, air conduction; dB, decibel; PTA, pure tone audiometry; SD, standard deviation.
[a]Unpaired *t*-test.

Shankar et al in their study and Sharma et al in their study.[13,16] In a meta-analysis by Tan et al, similar finding was observed. The findings emphasize the fact that tympanoplasties should not be postponed till the ear becomes dry as it can take up to 3 months or more in some cases. Earlier it was believed that cortical mastoidectomy provided benefit by improving the aeration of mastoid and middle ear. However, recent studies have shown that cortical mastoidectomy will not provide any additional benefit in terms of graft uptake or hearing outcome.[12] It can also be extrapolated that closure of TM may actually aid in reduction in bacterial load and help in healing of the middle ear mucosa by reducing the inflammation and mucopus. Furthermore, patients who are from remote areas will have difficulties with frequent follow-up visits in that waiting period. Hence, we recommend that surgeons should make an attempt to render the ear inactive by topical and/or systemic antibiotic according to the regional protocol and can consider early surgery without waiting for 3 months period to make the ear completely dry. We also recommend studies in one's own center with large population to further validate the statement.

Various factors that affect the outcome of tympanoplasties have been studied. The commonly studied ones are

patient's age, gender, smoking, size of perforation, site of perforation, presence of septal or adenoid pathology, type of graft used, etc.[11,15] After literature search, it has been found that the effect of altitude has not been studied commonly. In a retrospective study by Konishi et al, the effect of air travel was studied on graft healing rates after tympanoplasty. However, other parameters like graft position and hearing outcome were not considered in that study.[17] In our study, all surgeries were performed in our center located at an altitude of 4,757 ft (1,450 m). The case series that are reported previously are from plain areas.[13,16,18] The success rate in our study was 92% in both AGroup and IAGroups. Shankar et al reported success rates of 80% in active and 88.6% in inactive ears without any statistically significant difference between both.[13] Sharma et al reported success rates of 94% in inactive ear and 100% in active ear without any statistically significant difference between both.[16] Naderpour et al reported a success rate of 93%; however, the status of the ear, that is, active or inactive, was not mentioned.[11] The success rate in our study is comparable to other studies reported from elsewhere.

In a study by Thornton et al, it was speculated that altitude can affect middle ear diseases among patients who lived in high altitude and low altitude areas.[19] The effect will become more evident in patients with associated nasal pathology or eustachian tube dysfunction.

High-altitude areas can have problems of poor connectivity between the patient's home and the hospital that can affect the patient follow-up. Patient staying in a low-altitude area will have to travel to the center that is in high altitude thereby creating changes in middle ear pressures and can possibly result in change in graft position.

Strengths and Limitations of the Study

It was a prospective cohort study conducted in a hilly area. The audiological outcome has been reported as per AAOHNS guidelines and recommendation. However, the sample size was small owing to the effect of ongoing Corona virus pandemic.

Conclusion

The success rates for our tympanoplasties for active and inactive COM performed in a hilly area were comparable to those reported from other centers. We would like to conclude that altitude may not negatively affect the outcome of tympanoplasty and that the active COM can have the similar success rate as inactive COM tympanoplasty. However, large sample sized studies from different hilly areas are needed to further validate the statement.

Conflict of Interest
None declared.

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