

TYMPANOPLASTY TYPE I EVALUATION OF THE SURGICAL RESULTS AND ITS IMPACT AS THE TREATMENT MODALITY IN CHRONIC OTITIS MEDIA

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ABSTRACT

BACKGROUND

Chronic Otitis Media (COM), mucosal disease is a common ailment with which patients present to the ENT outpatient department. Tympanoplasty is the surgery performed with the goals of establishing an intact tympanic membrane, eradicating middle ear disease, creating an air-containing middle ear space and restoring the hearing by building a secure connection between the eardrum and the cochlea. The success of tympanoplasty depends on various factors including patient factors, disease factors and surgical factors.

The aim of the study is to assess the present status and impact of tympanoplasty as the surgical treatment modality in cases of COM mucosal disease.

MATERIALS AND METHODS

50 patients were selected by non-probability convenience method of sampling and were assessed prior to surgery. Tympanoplasty was carried out in all patients and they were assessed following surgery at 3, 6 and 12 months, respectively. Statistical analysis was done of the improvement following tympanoplasty.

RESULTS

The analysis carried out revealed the graft take up rate to be 86% with failure in 7 (14%) patients. Of the factors contributing to failure following tympanoplasty, the statistically significant factors in this study were the status of middle ear mucosa and the status of the opposite ear ($p < 0.05$). Tympanoplasty continues to be an effective surgical modality of management in patients with COM, mucosal disease with a guarded prognosis in those having bilateral disease and persistent mucosal disease of middle ear cleft.

CONCLUSION

Tympanoplasty is the definitive and effective surgical modality in management of patients with COM mucosal disease. Of the factors considered relevant in the success of tympanoplasty, the status of middle ear mucosa and status of the opposite ear were found statistically significant in this study.

KEYWORDS

Chronic Otitis Media, Mucosal Disease, Tympanoplasty.

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BACKGROUND

Chronic Otitis Media (COM) is a chronic inflammatory disease of the middle ear and mastoid that often results in partial or total loss of the Tympanic Membrane (TM) and ossicles leading to conductive hearing loss that can range in severity up to 60 dB. It is an important public health problem with substantial economic and societal costs. A conservative estimate of the number of people in the world suffering from COM is over 20 million.¹

Majority of the patients with COM do well with antimicrobial therapy, but despite this, there is a subset of the patients who develop serious complications from this, otherwise self-limiting disease. Standard treatments for CSOM include debridement, ototopical therapy and dry ear precautions. In those cases that do not resolve or result in spontaneous healing of the tympanic membrane with conservative measures, surgical intervention is considered. The main goals of surgery include eradication of the disease, prevention of recurrence and preservation or improvement of hearing. In the past, most workers described success of tympanoplasty in terms of hearing improvement only, when in fact elimination of infection and preservation or restoration of anatomy is also of equal importance. Therefore, in the present era, the results of tympanoplasty need to be reassessed keeping in mind all the various factors likely to change its final outcome. It is not possible to study all the factors together and hence this

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study analyses the effect of disease factors on the success of tympanoplasty type I.

MATERIALS AND METHODS

A total of 50 patients of COM, mucosal disease above 18 years of age, attending the ENT outpatient department at the tertiary care service hospital since August 2013 constituted the study population of this prospective study. All patients included in the study had a benign central perforation in the pars tensa of the tympanic membrane and were treated sufficiently to ensure a dry ear at least 8 weeks prior to the surgery. Patients with perforation of tympanic membrane owing to other causes, i.e. trauma and those with an actively discharging ear were excluded from the study.

Inclusion Criteria

- Patients who present to the Department of Otorhinolaryngology at the OPD with COM, tubotympanic disease, i.e. having discharge from the ear for more than 3 months and with a benign central perforation in pars tensa of the tympanic membrane.
- Patients treated sufficiently to ensure a dry ear at least 8 weeks prior to the surgery.
- Patients in the age group 18-60 years.

Exclusion Criteria

- Patients with an acute exacerbation of chronic otitis media, i.e. actively discharging ears.
- Patients with central perforation due to other causes like trauma.
- Patients with bilateral chronic otitis media where the ear to be operated is the only hearing ear.
- Patients <18 years and >60 years.

All patients underwent complete evaluation, which included otoscopic examination and pure tone audiometry. The otoscopic evaluation included assessment of size of the perforation, location of the perforation, status of middle ear mucosa and status of the opposite ear. The assessment was performed by the principal author to minimise the subjective variations likely. The size of perforation was graded as small (less than 25%), medium (25% to 50%), large (more than 50%) and subtotal (more than 75% or whole of pars tensa except the annulus) and the location of the perforation was noted whether in the anterior half or posterior half or both. The status of the middle ear mucosa was assessed and recorded as normal or oedematous wherein oedematous included patients who continued to have hyperaemic or polypoid middle ear mucosa status, despite 3-4 weeks therapy with systemic antibiotics and decongestants. The status of the opposite ear was recorded as normal, scarred, operated or with evidence of disease. All the patients underwent preanaesthetic checkup prior to surgery. The surgery tympanoplasty type I was performed under local anaesthesia except for apprehensive and anxious patients who desired general anaesthesia. The material used for the graft was the autologous temporalis

fascia and was placed by underlay technique. Thus, the surgical technique used remained more or less uniform. The postoperative assessment of the patients was done at 3, 6 and 12 months after the surgery wherein otoscopic evaluation and pure tone audiometry was repeated. In this study, success was defined as an intact tympanic membrane following surgery and the success rate was then evaluated for each category of interest.

The data so obtained was analysed using the Chi-square test of significance. The hearing results ABG (Air Bone Gap) in PTA (Pure Tone Audiometry) before and after surgery was analysed using the t-test. All the patients were counselled about the nature of the study and informed consent was taken.

RESULTS

The mean age of the patients who underwent tympanoplasty type I was 34.7 years and the study population included 26 males and 24 females. All the patients underwent tympanoplasty type I, 92% under local anaesthesia and 8% under general anaesthesia. The approach was post aurial in 80% patients and endaural in 20% patients. The endaural approach was taken for patients who had a wide external auditory canal and for perforations in both quadrants predominantly anterior. It was the right ear operated in 44% patients and left ear in 56% patients. The preoperative assessment of the otoscopic evaluation with respect to each factor analysed was carried out. Postsurgery, the patients were assessed at timely intervals as stated wherein both otoscopic examination and pure tone audiometry were performed.

In this study, 74% of the patients had a small-to-moderate size perforation and 26% had a large to subtotal perforation (Figure 1). In terms of location of the perforation, 56% patients had perforations in the anterior half, 10% had perforations in both anterior and posterior half and 34% patients had the perforation in the posterior half (Figure 2). The status of the middle ear mucosa was assessed preoperatively, wherein 24% patients in the study had an oedematous middle ear mucosa and 76% patients had a normal middle ear mucosa (Figure 3). The status of the opposite ear was normal in 60% and 40% had either an old healed, scarred tympanic membrane or presence of a bilateral disease (Figure 4). The size of the perforation and the location of the perforation did not influence the results of surgery. On statistical analysis, the status of the middle ear mucosa and the status of the opposite ear were found to be statistically significant factors influencing the success following tympanoplasty as summarised in Table 1.

In this study, the improvement in hearing was analysed using an ABG closure of less than; <20 dB as significant following surgery. On PTA done preoperatively, 44% patients had an AB gap >20 dB; following tympanoplasty at 3 months, 90% patients had AB gap <20 dB and at one year 88% patients had AB gap <20 dB, respectively (Figure 5). The improvement in hearing following tympanoplasty was statistically significant at six months and one year following surgery ($p < 0.05$) summarised in Table 3.

Therefore, the assessment of improvement in hearing must be carried out only after 6 months of tympanoplasty and preferably at one year following tympanoplasty. The improvement in hearing following tympanoplasty was statistically significant at one year following surgery as shown in Table 2.

Otoscopic Examination- Size of Perforation (Sz)

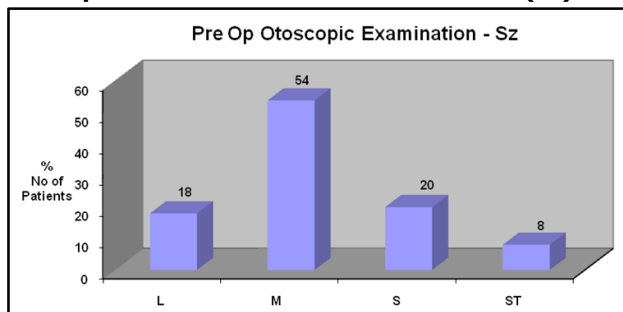


Figure 1. Preop Otoscopic Examination - Sz

In this study, 74% of the patients had a small-to-moderate size perforation and 26% had a large to subtotal perforation. The size of the perforation was an otoscopic finding assessed as a factor contributing to the success of the surgery.

Otoscopic Examination- Location of Perforation (LP)

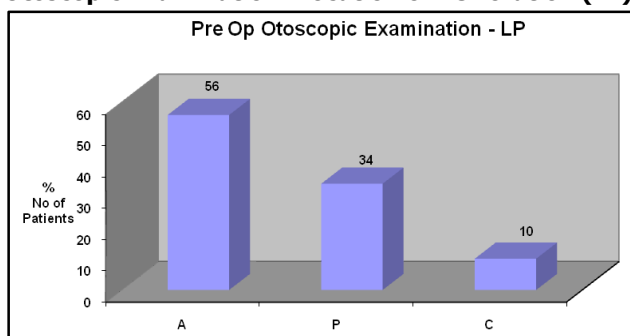


Figure 2. Preop Otoscopic Examination - LP

In this study, 56% patients had perforation in the anterior, 34% patients had the perforation in the posterior quadrant and 10% had perforation occupying both the anterior and posterior quadrants. The location of the perforation was assessed as a factor contributing in the success following tympanoplasty.

Otoscopic Examination- Status of Middle Ear Mucosa (MEM)

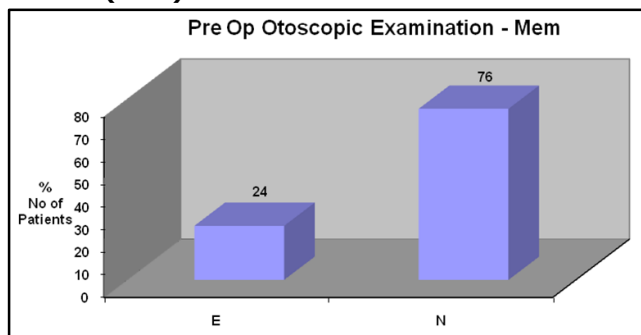


Figure 3. Preop Otoscopic Examination - MEM

The status of the middle ear mucosa was assessed preoperatively. 24% patients in the study had an oedematous middle ear mucosa and 76% patients had a normal middle ear mucosa. The presence of an oedematous middle ear mucosa was considered as an indicator of a persistent middle ear disease.

Status of the Opposite Ear

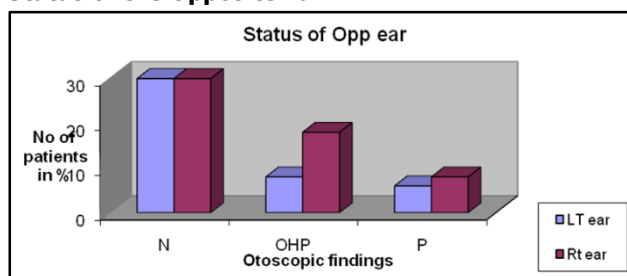


Figure 4. Status of the Opposite Ear

In this study, the status of the opposite ear was normal in 60% and 40% had either an Old Healed Perforation (OHP), scarred TM or presence of a bilateral disease (P). The analysis of both ears plays a key role in the prognostic assessment of each patient and hence the status of the opposite ear was evaluated as a factor influencing the success following tympanoplasty.

The Statistical Analysis of Otoscopic Findings Using Chi-Square Test

Objective Parameters Analysed	p-value
Size of the perforation	0.2878
Location of the perforation	0.4843
Status of middle ear mucosa	0.0009
Status of the opposite ear	0.0329

Table 1

In this study, the analysis of the otoscopic findings before and after surgery was carried out using the Chi-square analysis. The size and location of the perforation did not influence the success following tympanoplasty. The statistically significant factors contributing to the success of tympanoplasty were-

AB Gap >20	Preop	3 Months	6 Months	1 Year
PTA_AB_Gap_RT	11	3	3	3
PTA_AB_Gap_LT	11	2	3	3

Table 2. Assessment of Hearing Air Bone Gap (ABG) analysis

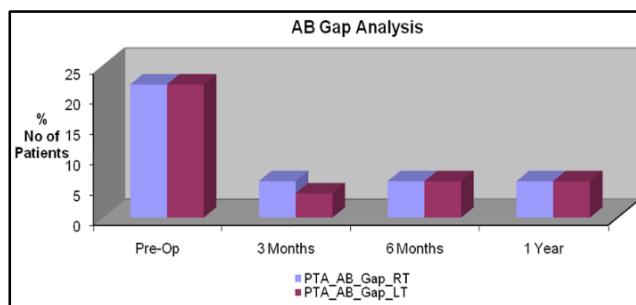


Figure 5. AB Gap Analysis

In this study, 44% patients had an ABG >20 dB; after tympanoplasty at one year 12% had an ABG >20 dB and there was an improvement in 32% patients. The improvement in hearing was significant on assessment after one year of surgery with 88% patients having an ABG <20 dB.

Comparison of the Hearing Results before and after Surgery using the t-Test

Pure Tone Audiometry ABG		
Category	Rt.	Lt.
Preop vs. 3 months	0.1136	0.1554
Preop vs. 6 months	0.0262	0.0345
Preop vs. 1 year	0.0219	0.0379

Table 3

In this study, the improvement in hearing was analysed using an ABG closure of <20 dB as significant following surgery. On PTA done preoperatively, 44% patients had an AB gap >20 dB; following tympanoplasty at 3 months, 90% patients had AB gap <20 dB and at one year 88% patients had AB gap <20 dB, respectively. The improvement in hearing following tympanoplasty was statistically significant at six months and one year following surgery (p <0.05).

DISCUSSION

Tympanoplasty is the definitive surgical management for COM mucosal disease. Even today, four decades after its introduction, it continues to be a challenge to the otorhinolaryngologist. Tympanomastoid surgery is quite successful in controlling infection and preventing recurrent disease with reported success rate in excess of 80-90%.² In this study, the success rate was found to be 86%. Functional success after tympanoplasty surgery is only partly determined by the surgeon’s technical skill. Other factors can also play a significant role such as the ability of the middle ear mucosa to heal appropriately and the ability of the ear to aerate itself at normal static pressure. The latter can change over the course of months or years, which in turn can significantly affect the acoustic transmission properties of the reconstructed ear.

Vartiainen E and his colleagues in their results of 404 primary myringoplasty operations that were critically analysed found an overall success rate of 88 percent with a mean follow up period of 5.5 yrs.³ There are various factors that interfere in the success following tympanoplasty and attempts have been made each time to ascertain these, so as to improve the final result following surgery. In this study, the improvement in otoscopic findings and hearing results following tympanoplasty were assessed with analysis of the statistically significant factors that affect the success of tympanoplasty.

Bhat NA et al in their study of patients with COM reported that the factors that may influence the success rates of tympanoplasty are- age, perforation location and size, eustachian tube conditions, status of the middle ear mucosa, type of graft used and surgeon experience.⁴ Ilana

Fukuchi et al in their study found that parameters such as perforation size and location, eustachian tube status, middle ear mucosa status, type of graft used and others hereby mentioned, such as disease development, number of infections per year, percentage of membrane involved in the perforation or monthly income did not prove to be statistically important for obtaining surgical success.⁵

The role of the prognostic factors and middle ear risk index on the success of tympanoplasty has been studied.⁶ The overall success rate was 74.4% and size of the perforation (<50%), healthy opposite ear, absence of myringosclerosis, more than 3 months dry period and low middle ear risk index were found to be significant independent prognostic factors. Many authors believe that the perforation location plays a more important role in surgery success than perforation size.^{5,7} Perforations in the anterior quadrant of the tympanic membrane represent a worse surgical access in order to reach the anterior border and they are also less vascularised owing to which they are considered an important success factor for surgery. Hallik JJ et al in their long-term results of tympanic membrane repair found that the anterior perforations healed more poorly.⁸

The middle ear mucosal status suggests disease activity. Thus, if there is mucosal hyperplasia, this may mean poor aeration of the middle ear suggesting disease activity. Therefore, studies show that with a minimum interval of three months without otorrhoea, the surgery success rate increases to more than 30% when compared to the cases that underwent surgery in an infected site.⁹ Recurrent infection poses a greater problem in the subgroup of patients with active COM with granulation tissue, but without cholesteatoma when compared to COM with cholesteatoma.¹⁰ The hypothesis that has been forwarded is that this subset of cases of COM with granulation tissue maybe the result of an inherent problem in the mucous membrane and hence more difficult to eradicate by surgical means.

Aviles Jurado FJ et al in their study found that the contralateral ear pathology and the perforation extension were associated with poor prognosis after myringoplasty.¹⁰ Common reasons for failure of tympanoplasty are total or partial non-aeration of the middle ear and development of negative static pressure. Total non-aeration of the middle ear is due to eustachian tube dysfunction and can lead to severe tympanic membrane atelectasis, middle ear effusion and fibrocystic sclerosis of the middle ear or a combination of these changes. In some patients, the problem is selective non-aeration of the posterior mesotympanum due to deposition of fibrous tissue, while the anterior mesotympanum and protympanum remain well aerated.¹¹ Many postoperative ears exhibit a tendency to develop negative static pressure in the middle ear. Over the long term, this negative pressure leads to retraction and atelectasis of the reconstructed tympanic membrane and functional compromise as well as a predisposition to displacement or extrusion of ossicular prostheses. Our present knowledge of normal eustachian tube function and

dysfunction is inadequate and elucidation of its pathophysiology is central to a clinical understanding of COM and to the success of tympanoplasty.

Postoperative hearing outcomes were considered successful, if the postoperative air-bone gap was within 20 dB. In this study, prior to surgery, 44% patients had an ABG >20 dB and following tympanoplasty at one year, it was noted that 88% patients had an ABG <20 dB. There was an improvement in hearing postsurgery with no significant worsening in symptoms noted even with persistent small perforation. In the study by Ilana Fukuchi et al, the audiometric gain was found in most of the patients after the first surgery and in 100% of the patients after reoperations. They believed that this hearing improvement is due to the fact that there was a reduction in perforation size in most of the patients' studied.¹²

CONCLUSION

As any other surgery, the success following tympanoplasty depends on various factors including disease factors, patient factors and treatment factors. It is essential to optimise conditions prior to surgery in order to ensure the best result post-surgery. Tympanoplasty remains to be the definitive surgical management for COM, mucosal disease with various factors affecting its final outcome. It is observed that patients with bilateral disease and persistent mucosal disease of middle ear have a guarded prognosis. There is a need for further randomised control trials to assess the surgical and patient factors as well as success with other types of tympanoplasty. The results of these would help improve the outcome of tympanoplasty by enabling improvement of the poor prognostic factors identified and also predict outcome of surgery on the basis of existing conditions.

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