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Hearing Outcome After Type I Tympanoplasty Using Temporalis Fascia as Graft: A Prospective Study

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Key Words
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Abstract
Study of hearing outcome after type 1 tympanoplasty using temporalis fascia as graft and factors influencing it like Age, Socioeconomic status, Size of the perforation, Duration of dry ear, Presence of tympanosclerotic patch over tympanic membrane and comparing our pre and post operative audiological results with that of previous studies. A total of 80 patients with CSOM who underwent type I tympanoplasty in the department of E.N.T, at Sree Mookambika Institute of Medical Sciences were studied during the period of 18 months (December 2022 to May 2024). A detailed preform was taken for each patient regard to personal details, clinical history and examination, investigations, surgical procedures, pre and post operative follow up visits. Audiological evaluation using pure tone audiometry done pre operatively, 3 and 6 months post operatively. Results are tabulated. Statistical analysis done. In our study of 80 cases the mean graft take up is 91.25% and mean hearing gain is 12.16dB. Incidence of cases is more in the age group of 20-29 years (47.5%) and graft take up and hearing gain in younger age group (94.11% and 12.23dB), Female patients (91.06% and 13.02dB), Middle class people (95% and 12.64dB), patients with normal opposite ear (96.5% and 13.06dB), dry ear for more than 6months (95.45% and 13.5dB), perforation size (93.54% and 12.03dB in <50% size: 83.33% and 14.81dB in >50% size), absent tympanosclerotic patch over tympanic membrane (93.93% and 12.75dB), pneumatic mastoid (92.85% and 13.5dB). Status of the opposite ear, size of the perforation, duration of dry ear, presence or absence of TSP over Tympanic membrane, presence of pneumatic mastoid has a significant role in the outcome of type I Tympanoplasty.

INTRODUCTION

Chronic suppurative otitis media is one of the major causes for tympanic membrane perforation in our country. The vast majorities of perforations due to infection are small and heal spontaneously[1]. Persistent of perforation can lead to recurrent infection of the middle ear and conductive hearing loss of about 30 to 40dB. Closure of the perforation along with disease clearance was attempted since many years.

Myringoplasty and Tympanoplasty are descriptive terms defining surgical procedures that address pathology of the tympanic membrane (TM) and middle ear. Myringoplasty is an operative procedure used in the reconstruction of a perforation of the tympanic membrane. This assumes that the middle ear space, its mucosa and the ossicular chain are healthy. Tympanoplasty implies reconstruction of the hearing mechanism and also deals with pathology within the middle ear cleft, such as chronic infection, cholesteatoma, or an ossicular chain problem[2].

Tympanoplasty is the final step in the surgical conquest of conductive hearing losses and is the culmination of over 100 years of development of surgical procedures on the middle ear to improve hearing. Different technique and different graft materials are used like Temporalis Fascia, Duramater, Perichondrium and various factors influencing the outcome are studied.

In 1965, the American Academy of Ophthalmology and Otolaryngology Subcommittee on Conservation of Hearing defined tympanoplasty as "a procedure to eradicate disease in the middle ear and to reconstruct the hearing mechanism, with or without tympanic membrane grafting." This operation can be combined with either an intact canal wall (ICW) or a canal wall down (CWD) mastoidectomy to eradicate disease from the mastoid area.

MATERIALS AND METHODS

The present study of was done in Sree Mookambika Institute of Medical Sciences, Kulasekharam, during the period between December 2022 and May 2024. Patients presenting to the outpatient department and fulfilling the below mentioned criteria were taken up for study. The inclusion criteria were 1. Patients of both sexes of age between 15-45 years presenting with perforated tympanic membrane due to chronic otitis media, trauma, recurrent middle ear infection, in which ossicular systems are mobile and intact. 2. Dry ear. 3. Eustachian tube function is intact. Exclusion criteria were 1. Patients with Sensory neural hearing loss (SNHL). 2. CSOM with attico-antral type.3. Disease causing disruption and damage to ossicular chain like tympanosclerotic, middle ear atelectasis, middle ear tumors, congenital cholesteatoma etc. A detailed proforma was filled for each patient with regard to history, clinical examination, investigations, surgical procedures, postoperative period and follow up visits. Audiological evaluation (pure tone audiometry) done preoperatively, 3 months and 6months after. Surgery and the results are tabulated. Graft materials used for the procedure was autologous temporalis fascia. It was done under local anaesthesia or general anaesthesia. Post operatively Antibiotic, analgesics and oral decongestants are administered for 14 days. Mastoid dressing applied for 24-48 hours. Antibiotic ear drops advised for 3 weeks, three times a day.

External auditory canal pack was removed after 3 weeks, neo tympanic membrane was inspected, patients were told to follow-up regularly at weekly intervals to note the graft take up for 3 months. Audiological evaluation was done postoperatively after 3 months. The outcome was taken as Successful – If at the end of 3 months the graft was still in situ and acted as a scaffold for the epithelial healing and an effective hearing gain of at least more than 10 dB. Failure – If there was graft rejection after 3 months or if there was hearing gain of less than 10 dB.

RESULTS AND DISCUSSIONS

In our series we studied 80 ears (80 patients) of type 1 tympanoplasties. The age and sex incidence and various factors influencing the audiological benefit in a successful type 1 tympanoplasty were analysed after 3 months and 6 months and the results were analyzed based on the observations of the second follow up audiogram (after 6 months). Patients under 15 years of age were not included in this study. Upper age limit was 45 years as many patients above this age showed mixed hearing loss. In this study maximum numbers of patients (38) were seen in the age group of 20-29 years (47.5%). There were 8 patients (10%) in the age group of 10-19 years, 28 patients (35%) in 30-39 years and 6 patients (7.5%) in the age group of 40 -50 years.

In our study there were 34 cases below 28 years of age in which 32 cases showed graft take up of 94.11% and the mean hearing gain of 12.23dB and 46 cases were 28 years and above age showed graft take up of 91.11% and mean hearing gain of 12.9dB. Out of the 80 cases 44 (55%) patients were male and 36 (45%) were female, with the ratio of 1.22:1 in favour of male. In our study of 80 cases, 60 cases (75%) belonged to low socioeconomic group and 20 cases (25%) belonged to middle class group. None of the patients were in the high socioeconomic group.

About 22 (27.5%) cases were bilaterally affected, Right ear was involved in 26 (32.5%) cases and Left ear was involved in 32 (40%) cases. In our study 58 (72.5%) of our patients had dry ear since 1-6 months and 22(27.5%) had dry ear for more than 6 months. Around 33 cases (41.25%) had small size perforation, 29 cases (36.25%) had medium size perforation, 12cases (15 %)

Table 1: Ear affected and outcome

	Unilateral	Bilateral
Graft take up (%)	96.5	77.27
Hearing gain (dB)	13.06	10.93

Table 2: Graft status

	No of cases	Percentage
Taken up	73	91.25
Not taken up	7	8.75

Table 3: Hearing gain(mean)

Mean pre-operative pure tone average(dB)	Mean post-operative pure tone average(dB)	Mena hearing gain (dB)
33.81	21.65	12.16

had large size perforation and 6 cases (7.5%) had subtotal perforation. Tympanosclerotic patch over the tympanic membrane was absent in 66 (82.5%) cases and in rest of the 14 (17.5%) cases it was present. We used temporal fascia graft in all 60 cases, 28 cases (35%) had pneumatic mastoid and 52cases (65%) had sclerotic mastoid.

Out of 80 cases, which had undergone Type 1 tympanoplasty in our hospital, there was graft take up in 73 cases (91.25%) and in 7 cases (8.75%) graft did not take up. In our study the mean pre-operative hearing loss was 33.81dB, mean post- operative hearing was 21.65dB and the mean hearing gain is 12.16dB.

Michael and Glasscock[4] report in their study of 1556 tympanic membrane grafting that there was no difference in take rate of graft based upon age of the patient. In Ortegren's study, the hearing improvements in the various groups below 30 years were obviously very much alike. Hearing results were worse in the above 30 years age group, compared to young age group and in his study the maximum number of the patients were in the age group of >30 years (42.5%). Vartiainen[5] found that results in elderly patients were found to be as good as in younger patients. In our study of 80 cases age below 15 years and above 45 years are not considered. According to the available literature, unless there is Cholesteatoma or a bilateral tympanic membrane perforation with conductive hearing loss, tympanoplasty in children can be delayed until the age of 10-15 years, when Eustachian tube function is usually better and a satisfactory outcome is more likely[6]. Distribution of age showed maximum number of cases in the age group between 20-29 years in contrast to study done by ortegren where most of the cases are above 30 years. It purely depends on the age group from which we select maximum number of cases and statistically it is not significant.

The mean age of our study sample was 28 years. To know the age factor in the outcome of the surgery we divided the sample into age below 28 years and age of 28 years and above. The hearing results in patients below 28 years (12.23dB of hearing gain and 94.11% graft take up) are compared with patients of age 28 years and above (12.9dB of hearing gain and 91.11% graft take up). The graft take up was more in age group below 28 years and hearing gain was slightly more in age group of 28 years and above. As described by many studies graft take up is more in younger age groups but if the cochlear reserve is good then same outcome can be achieved in elderly people also but both the value are statistically not significant (p is >0.05) indicating that there is no significant relation between age factor and outcome of type I tympanoplasty.

Caye-Thomasen[7] in their study of 26 cases, male to female ratio was 1.36. Booth (1974) reported that there are more failures in women than men with regard to graft take up rates. In our study male to female ration is 1.22. Graft take up rate is slightly more in female (91.6%) compare to male (88.63%). Hearing gain is also slightly more in female (13.02dB) compare to male (12.26dB) but both these results are not significant statistically. This may be due to females becoming more conscious regarding the hearing loss, increasing female literacy rate. As per the available literature there is no difference in outcome of surgery solely on the basis of gender[8].

Browning GG[9] states that there is a close relationship of chronic otitis media and low socio economic group. Higher incidence and poor surgical outcome is because of poor general health, malnutrition and overcrowding. In our study maximum percentage (75%) of patients belongs to low socioeconomic status. Compare to low socioeconomic group, patients in middle class group showed slightly better rate of graft take up and hearing gain. But there was no any strong significant relation between these two factors and the results are statistically not significant.

Robert K Jackler and Robert A Schindler[10] in their study of 48 patients, bilateral tympanic membrane perforation was seen in 25% of patients. John B Booth[11] in his study of 284 cases, found the incidence of bilateral discharge to be 30%. The status of the contra lateral ear was found to be a prognostic factor by Koch[12] but not by Chandrasekhar[12]. William O. Collins, MD[14] in his study the presence of perforation, high negative pressure, atelectasis and OME in the contralateral ear was associated with a less successful outcome for obtaining adequate middle ear aeration. Caution should be exercised in performing tympanoplasty in patients with ongoing Eustachian tube-middle ear dysfunction in the contralateral ear.

In our study of 80 cases, 26 cases (32.5%) had right ear disease, 32 cases (40%) had left ear disease and 22cases (27.5%) were having bilateral disease. This correlates well with the quoted literature. In our study the graft take up and hearing gain was 96.5% and 13.06dB when the contra lateral ear was normal and 77.27% and 10.93dB when it is diseased which is statistically significant(p value is <0.0001). Thus the status of the contra lateral ear can be considered as

one of the prognostic factor indicating the role of Eustachian tube function in tympanoplasty.

Brown C[15] in their study of 193 cases of tympanoplasty found the success rate to be 75% if perforation is dry and 64% success rate if the perforation is wet. Gibb AG, Chang SK[16] in their study of 206 cases of underlay Myringoplasties, found that the uptake rate of 91.4% for dry ears and 80.9% for wet ear. In our study of 80 cases, 58 cases had dry ear preoperatively between 1 and 6 months, of which 89.65% had graft uptake, while 22 cases had dry ear preoperatively for more than 6 months, which had a graft take up rate of 95.45 % which correlates with the quoted literature.

The hearing gain is 12.24dB is patients who had dry ear preoperatively between 1-6 months and 13.5dB in patients who had dry ear for more than 6 months indicating the role of dry ear as one of the prognostic factor for successful tympanoplasty. Dry ear for long duration indicates disease free middle ear cleft which directly affects the surgical outcome. So the outcome of the surgery will be better if the operating ear is dry for long duration.

Adkins and White[17] proposed that the two factors which adversely influenced the success rate were the presence of a near total or total perforation and the presence of bilateral perforations. In our study of 80 cases, 33 cases (41.25%) had small size perforation, 29 cases (36.25%) had medium size perforation, 12cases (15 %) had large size perforation and 6 cases (7.5%) had subtotal perforation. Perforation size of more than 50% had poorer graft take up rate (83.33%), in comparison to patients with perforation size of less than 50% (94.53%). The hearing gain was more in patients with perforation size of more than 50% (14.84dB) when compared to patients with perforation size of less than 50% (12.03%) this is because the pre-operative hearing deficit is more in case of patients with perforation size more than 50%, obviously the amount of hearing gain will be more in them indicating a significant (p is<0.0147) relation between size of perforation and outcome of surgery.

Kageyama-Escobar[18] in his study, presented 82% of closing of tympanic perforation and observed that tympanosclerosis was among the factors for surgical failure, mainly when it diffusely involved. In our study tympanosclerotic patch was absent in 66 (82.5%) cases and in rest of the 14 (17.5%) cases it was present. The graft take up rate was more in patients with absent tympanosclerotic patch (93.93%) than those with presence of tympanosclerotic patch (78.5%) which is statistically significant indicating that presence of TSP over the tympanic membrane significantly affects the graft take up. The hearing gain was 12.75dB in patients without tympanosclerosis and 11.72dB in patients with tympanosclerosis, which is statistically not significant indicating no major role in hearing gain.

Jackler and Schindler[19] found a strong correlation between mastoid pneumatization and results of type I tympanoplasty and suggested that the patients with larger (pneumatic) mastoid had higher successful results in comparison with patients with smaller (sclerotic) mastoid. In our study of 80 cases, we found that 52 cases (65%) had sclerotic mastoid, with a success rate of 90.38% and hearing gain of 12.11dB in comparison 28 cases (35%) had well pneumatic mastoid on X-ray, with a success rate of 92.85% and hearing gain of 13.5dB which correlates with the observation of the quoted literature but statistically the results are not significant.

Gibb AG, Chang SK[20] in their study of 206 cases of type I tympanoplasty employing the underlay technique with temporal fascia reported a Graft take rate of 89.3%. Robert K Jackler, Robert A Schindler (1984) 20 in their study of 48 cases reported a graft take rate of 85.4%. Michael E Glasscock (1982)44 in his study of post auricular undersurface tympanic membrane grafting, showed the graft take rate with fascia to be 93%. Albera R. 64 in their study of 212 patients, found a graft take rate of 86% (182 cases). In our study of 80 cases of type 1 tympanoplasty, 73 cases showed successful graft take up. The percentage of graft take up is 91.25% which is very nearly correlates with the quoted literature. Out of 7 failure cases, 5 cases are because of infection, poor hygiene and rest 2 cases are due to faulty technique correlating well with the quoted literatures.

CONCLUSIONS

The outcome of Type 1 tympanoplasty does not depend on Age, Sex and Socioeconomic status. Status of the contralateral ear is an important prognostic factor indicating the role of Eustachian tube in the successful outcome of the surgery. Pre operative dry ear status is directly related to the outcome of surgery. More the duration of dry ear, better will be the graft take up and hearing gain.

Graft take up is better in perforation size less than 50% when compare to perforation size more than 50%, but hearing gain will be more in perforation size of more than 50% because the patient is having more pre-operative hearing deficits in large perforations. Presence of tympanosclerosis patch over tympanic membrane decreases the graft take up rate and hearing gain. Sclerotic mastoid have poor graft take up rate and hearing gain. The type of graft material does not influence the successful outcome. Though the graft success rate was maximum with Duramater and tragal perichondrium graft the hearing restoration was maximum with Temporalis Fascia graft. Temporalis

Fascia remains the Gold standard and the most popular graft material for its unique qualities. In light of comparable results, Tragal Perichondrium, Duramater can be used for revision tympanoplasty with equally good results in cases where adequate Temporalis Fascia may not be available at the surgical site. Post operative infections and faulty technique are the most common causes for the graft failure.

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