International Journal of Otorhinolaryngology and Head and Neck Surgery
Singh SS et al. Int J Otorhinolaryngol Head Neck Surg. 2021 Jun;7(6):1031-1034
http://www.ijorl.com
pISSN 2454-5929 | eISSN 2454-5937

DOI: https://dx.doi.org/10.18203/issn.2454-5929.ijohns20212128

Original Research Article

Pre-operative and post-operative audiological evaluation of type 1 tympanoplasty and comparison between temporalis fascia graft and tragal perichondrium graft

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Received: 24 March 2021
Revised: 15 May 2021
Accepted: 18 May 2021

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ABSTRACT

Background: Aim of the study was to evaluate the hearing improvement of type 1 tympanoplasty performed by using autologous temporalis fascia and autologous tragal perichondrium graft in successfully operated and graft uptake cases, with respect to age, sex, size of perforation and type of graft.
Methods: This prospective study consists of total 100 patients with chronic suppurative otitis media (CSOM) tubotympanic disease who have undergone type 1 tympanoplasty. Randomization of patients was done. Every alternate patient was divided accordingly in to two groups-one in temporalis fascia graft group and another in tragal perichondrium graft group. Pure tone audiometry (PTA) was performed preoperatively and 3 months after surgery. Cases with successful graft uptake were included in the study. Statistical comparisons were performed using the t test, and ANOVA test.
Results: In this study maximum numbers of patients were found in the age group of 15-30 years. Study showed that audiological benefits were more in males in comparison to females. Large size of perforation showed more improvement due to more air bone gap in comparison to medium size and small size perforation of ears. Audiological improvement occurred in 94% of cases, 3% cases worsened and 3% cases showed no change. More improvement was found in temporalis fascia graft in comparison to tragal perichondrium graft.
Conclusions: Type 1 tympanoplasty is a safe and effective technique to improve the quality of life of patients. Size of perforation, type of graft was found to have a major effect on the final outcome of surgery.

Keywords: CSOM, Type 1 tympanoplasty, PTA, Hearing improvement

INTRODUCTION

Worldwide, complicated ear infection was a life-threatening disease. The invention of antibiotics and operative microscopes are ground-breaking in the surgical field and is a substantial development in disease control. Tympanic membrane perforation results in chronic ear infection and hearing loss.[1] Chronic suppurative otitis media remains an essential issue in our nation. Literature showed that various methods and various graft materials such as temporalis fascia, tragal perichondrium have been used to cure ear infections.[2-6]

Myringoplasty is an operation in which the reconstructive procedure is limited to repairing the perforation of the tympanic membrane, assuming that the middle ear ossicles function normally, eustachian tube is patent, and the patient has a good cochlear reserve, while

tympanoplasty is an operation in which the middle ear sound conductive apparatus is inspected and repaired along with tympanic membrane reconstruction.[3]

Pure tone audiometry is the key hearing test used to identify an individual's hearing threshold levels, allowing the degree, type and configuration of a hearing loss to be determined and thus providing a basis for diagnosis and management.[4-9] As it relies on patient's response to pure stimuli, PTA is a subjective, behavioural measurement of hearing thresholds. Therefore, PTA is used only for adults and children who are old enough to cooperate with the test procedure.

Aims and objective

Aim and objectives of the study were to compare pre and postoperative audiological status in successful type 1 tympanoplasty and to compare audiological outcome by using different graft materials (Autologous temporalis fascia and autologous tragal perichondrium).

METHODS

This prospective study consisted of 100 patients with CSOM tubotympanic disease who underwent type 1 tympanoplasty in the department of ENT and HNS Muzaffarnagar medical college and hospital, Muzaffarnagar in the period between Jan 2019 to May 2020. Ethical clearance was obtained from the institutional ethics committee.

Sample size was calculated using the following formula:

$$n = \frac{Z^2_{\alpha/2}\, p(\%)q(\%)}{d(\%)^2}$$

Where, p is the observed prevalence, q=100-p, d is the margin of error and $Z_{\alpha/2}$ is the ordinate of standard normal distribution at α% level of significance

Calculations

p (Prevalence of chronic suppurative otitis media)=5.11%
q=94.89%,
d=0.05%.
$Z_{2.5\%}$ =1.96 at α=5% level of significance
n=74.5
Hence the minimum sample size required in the present study is 75. Considering the error and attrition, the sample size was increased to 100.

Inclusion criteria included patients of both sexes presenting with perforated tympanic membrane due to chronic otitis media, trauma, recurrent middle ear infection, whom ossicular systems are mobile and intact, ear was dry and eustachian tube function was intact.

Patients with sensorineural hearing loss (SNHL) or mixed hearing loss, COM-squamous disease-, and disease-causing disruption and damage to ossicular chain like tympanosclerosis, middle ear atelectasis, middle ear tumours, congenital cholesteatoma etc., were excluded from the study.

Graft material used in the procedures was autologous temporalis fascia or autologous tragal perichondrium. Randomization of patients was done. Every alternate patient was divided into two groups-one in the temporalis fascia graft group and another in the tragal perichondrium graft group. Total of 50 patients were included in each group. Pure tone audiometry (audiological evaluation) was performed preoperatively and 3 months after surgery. Successful graft uptake cases were included in study.

Statistical analysis

SPSS software 24 was used for statistical analysis and for checking the statistical significance of test results, T test and ANOVA test was used in the study.

RESULTS

This section presents the results and discussion of the study. The sample included 63 males and 37 females with a mean age of 26.1 years. Table 1 presents the improvement in the type 1 tympanoplasty cases, where 94% patients' cases have improved, 3% cases worsened and no change is found in remaining 3% cases.

Table 1: Presents the improvements in type I tympanoplasty cases.

Hearing results	No of cases	Audiological benefits (%)
Improvement	94	94
No change	03	3
Worsened	03	3
Total	100	100

Table 2 presents the different grafts and audiological improvement in type I tympanoplasty. Equal cases were present in both types of grafts. More improvement (15.88 dB) was found in temporalis fascia graft, while less improvement in tragal perichondrium graft.

Table 2: Grafts and audiological improvement in type I tympanoplasty.

Types of graft	No of cases	Audiological benefit (Speech frequency) (dB)
Temporalis fascia	50	15.88
Tragal perichondrium	50	11.72
Total	100	

To compare the test results of temporalis fascia (T. F.) and tragal perichondrium (T. P.) t test has been used. The hypothesis for this-

Null hypothesis: T. F. and T. P. have same effect on the patient.

Alternative hypothesis: T. F. and T. P. have different effect on the patient.

Table 3: T test results.

Variables	T. F.	T. P.
Mean	16.06	9.3
Variance	51.608	46.5
Observations	50	50
Pooled variance	49.054	
Hypothesized mean difference	0	
Df	98	
T stat	4.825	
P (T≤t) two-tail	0.049	
T critical two-tail	1.98	

The t test results of T. F. and T. P. graft of type I tympanoplasty. Average value of T. F. is high in comparison to T. P. For hypothesis testing statistical t test has been used. P value is used as a standard to decide which hypothesis is acceptable. Here, p value is less than 5%, analysis failed to accept the null hypothesis. It shows that T. F. has more significant and substantial effect on patients in comparison to T. P.

Study also examined the size of perforation and audiological benefits among the patients. Three types of sizes have been analysed over the patients.

Table 4 presents the size of perforation of ear and audiological benefits in patients. Large size of perforation has more improvement in comparison to medium size and small size perforation of ears.

Table 4: Size of perforation of ear and audiological benefits.

Size of perforation	No. of cases	Audiological benefit (speech frequency) (dB)
Small	11	10.45
Medium	46	11.45
Large	43	14.06
Total	100	

ANOVA test is used because study is comparing the test results of more than two variables. Here the study analyses small, medium and large size perforation in the ear and improvement in them.

Null hypothesis: All ear perforation sizes have same improvement among the patient.

Alternative hypothesis: All ear perforation sizes have different improvement among the patient.

Table 5: ANOVA test summary.

Groups	Count	Sum	Average	Variance
Small	11	115	10.4545	63.47273
Medium	46	527	11.4565	57.00918
Large	43	605	14.0698	61.39978

The ANOVA test summary includes the total counts, sum, average and variance in the values. Small ear perforation sizes have 11 patients, medium size, 46 patients and large sizes have 43 patients. High variance has been noticed in the small ear size perforation.

For hypothesis testing study used p value for accepting or rejecting the hypothesis. Here p value is less than 5%, study failed to accept the null hypothesis. Alternative hypothesis was accepted and showed that large size perforation in the ear has more improvement than small and medium size perforation.

Table 6: ANOVA test results.

Source of variation	SS	Df	MS	F	P value	F crit
Between groups	201.979	2	100.9895	1.695	0.0488	3.090
Within groups	5778.931	97	59.57661			
Total	5980.91	99				

DISCUSSION

This section presents the detailed discussion of the results and analysis. Table 1 in this study shows 100 cases, in which 94 (94%) cases showed improvement in speech frequency; 3% cases worsened while 3% showed no change in the speech frequency. In the similar context, in 1994, permanent hearing loss was reported by Ghamdi et al in 3% of patients in their study.[10] On the other hand, Vartiainen et al had reported 11 audiological failures in their series. The cause of persistent hearing loss has been found to be due to fixation or erosion of ossicles overlooked by the surgeon.[8]

Gibb et al also discovered that the underlay technique can result in persistent conductive hearing loss. If the malleus handle is severely retracted, especially if it touches or adheres to the promontory, problems arise due to the possible decrease in the depth of the tympanic cavity

when the graft is placed medial to the malleus handle to solve this problem. Gibb et al suggested that the malleus could be left in its original retracted position and a split graft pulled on each malleus handle size and tucked 2-3 mm from the tip of the handle behind its upper part or amputated.[4]

In the study Table 2 shows the audiological improvement in speech frequency. Results show that temporalis fascia graft (15.88) has more improvement than tragal perichondrium (11.72) graft. T test results show the statistical significance of the results. Similarly, according to research conducted by Bawa et al the results were better in homograft dura-mater (84%) as compared to autograft temporalis fascia (76%).[8] However, Sai Kiran et al the audiological results were compared with temporalis fascia and tragal perichondrium, temporalis fascia graft gave more audiological benefit in comparison to tragal perichondrium.[11]

In the analysis part, Table 4 shows the correlation between perforation size of the ear and audiological benefits. It was discovered that the hearing gain improves post-operatively as the perforation size increases. There are not many studies done on the relation between the size of the perforation and the audiological advantage. This study supports Packer's findings in which it was found that it obviously benefited more pre-operatively in those with a higher hearing deficit than those with a minimum pre-operative hearing loss.[7]

The limitation of the present study is small sample size along sample taken from one area only. Hence further studies with larger sample size along with wider coverage of sample should be done.

CONCLUSION

The study concludes that type 1 tympanoplasty is a safe and effective technique to improve patient's quality of life. The study found that the hearing gain has improved more, postoperatively, as the size of perforation increases. There is a significant difference among the improvement seen with different graft materials-temporalis fascia and tragal perichondrium. Temporalis fascia graft gives more audiological improvement than tragal perichondrium graft. Size of perforation, type of graft was found to have a significant effect on the outcome of the surgery.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Wasson JD, Papadimitriou CE, Pau H. Myringoplasty: closure and audiological improvement impact of perforation size. J Laryngol Otol. 2009;123(9):973-7.
2. Perkins R. Grafting materials in reconstructive ear surgery and methods. Ann Sep Otol Rhinol Laryngol. 1975;84(4 Pt 1):518-26.
3. Kelly G, Lee P, Mills RP. Myringoplasty: does it matter what size the perforation is Clin Otolaryngol Allied Sci. 2002;27(5):331-4.
4. Gibb AG, Chang SK. Myringoplasty (A 365 operations review). J Laryngol Otol. 1982; 96(10):915-30.
5. Yung MW-Myringoplasty: hearing gain relative to the site of perforation. Laryngol Otol J. 1983;97(1):11-77.
6. James L, Sheehy, Anderson RG. Myringoplasty. A review of 472 cases. Ann Otol Rhinol Laryngol. 1980;89(4 Pt 1):331-4.
7. Packer P. What's best in Myringoplasty: Underlay or Overlay, dura or fascia? Laryngol Otol J. 1982;96:25-41.
8. Bawa GS, Khurana AS, Singh H. Comparative evaluation of Auto graft Temporalis fascia and Homograft duramaterin Tympanoplasty. Indian J Otolaryngol. 1987;39(3):102-3.
9. Vartiainen E, Nuutinen J. Success and pitfalls in myringoplasty: follow-up study of 404 cases. Am J Otol. 1993;14(3):301-5.
10. Al-Ghamdi SA. Tympanoplasty: Factors that influence the outcome of surgery. Ann Saudi Med. 1994;14(6):483-5.
11. Sai Kiran G, Krishna VC. A Prospective Observational Study of Temporalis Fascia with Tragal Perichondrium as Graft Material in Type I Tympanoplasty. Int J Sci Res. 2019;8(12):509-31.

Cite this article as: Singh SS, Parmar SM, Sood A, Saroha N, Chaudhary M. Pre-operative and post-operative audiological evaluation of type 1 tympanoplasty and comparison between temporalis fascia graft and tragal perichondrium graft. Int J Otorhinolaryngol Head Neck Surg 2021;7:1031-4.