A COMPARATIVE STUDY OF DIFFERENT TISSUES USED FOR TYMPANIC MEMBRANE GRAFTING

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ABSTRACT: OBJECTIVES: To Compare Different Tissues Used for Tympanic Membrane grafting. **DESIGN:** A Prospective, double blind, randomized study. **MATERIAL AND METHOD:** The study was conducted on 75 patients with 80 ear disease having Safe or Tubo-tympanic type of Chronic suppurative Otitis media. Type-1 Tympanoplasty was done using various graft materials. **RESULTS:** The result shows that Graft success rate was maximum with Fascia Lata graft (95%) followed by Tragal Perichondrium (90%). For Temporalis Fascia and Tragal Cartilage grafts, success rate was same i.e. 85%. They achieve comparable and excellent graft take-up of 88.75%. They also achieve comparable and good hearing restoration. **CONCLUSION:** It was concluded that various autograft materials for Tympanoplasty achieved comparable and excellent graft take-up and comparable and good hearing restoration. The Graft success rate and mean hearing improvement (A-B gap closure) for different graft materials shows similar success rate and hearing improvement respectively.
KEYWORDS: Tympanoplasty. Chronic suppurative otitis media (CSOM). Temporalis Fascia. Tragal Perichondrium. Tragal Cartilage. Fascia Lata. Hearing impairment

INTRODUCTION: Chronic Otitis Media is the chronic inflammation of mucoperiosteal lining of the middle ear cleft characterized by ear discharge, a permanent perforation of the Tympanic Membrane and impairment in hearing. It is one of the most common ear diseases encountered in developing countries because of poor socioeconomic standards, poor nutrition, lack of health education and unhygienic habits[1, 2, 3,] . It is a major cause for deafness in India.

Tympanoplasty is the final step in the surgical conquest of conductive hearing losses and is the goal of Tympanoplasty is to control the disease, and to restore normal anatomy and hearing[4].

A critical problem early in the development of Tympanoplasty was finding an ideal graft material for Tympanic membrane grafting which is still in debate. The evolution of tympanic membrane grafting has been based on biological tissues of mesodermal origin which contain collagen matrix[5], when applied to seal the perforation and subsequently revascularize with migration of fibroblasts and epithelium. These graft materials vary regarding their ease of harvesting, preparation time, placement ease, viability and consequently the graft uptake and hearing improvement. Graft materials also show a wide variation in its dimensional stability.

Keeping all these factors in mind, the present comparative study of different graft material i.e. Temporalis Fascia, Tragal Cartilage, Tragal Perichondrium, and Fascia Lata in Underlay Tympanoplasty was undertaken to evaluate the postoperative Graft take-up and Hearing improvement.

MATERIALS AND METHODS: A prospective study was carried out from November 2009 to May 2011. Type-I Tympanoplasty by underlay technique, using appropriate incisional approach for all the cases selected for the study. Any patients requiring ossiculoplasty were subsequently excluded from the study.

Out of 75 cases with 80 ears disease, Temporalis Fascia grafts was used in 20 ears (Group I), Tragal Perichondrium graft in 20 ears (Group II), Tragal Cartilage in 20 ears (Group III) and Fascia lata graft in 20 ears (Group IV). Cases were allocated in different groups by randomization (Random allocation software 2.0).

Cases were selected for the study based on following criteria's: Patient with age above 15 years and below 60 years were included in study. Patients having Chronic Otitis Media of Safe or Tubo-tympanic type having Moderate, Large and Subtotal central perforation with Good Eustachian Tube function were included. All patients had adequate Cochlear reserve without any primary focus of infection (if present was adequately treated and surgery was performed after one month).

Patients having active ear discharge (discharge less than one month) or having any obvious Ossicular Dysfunction /Ossicular fixation during surgery (intra-op) is treated accordingly and excluded from study. The patients with complications of chronic Suppurative Otitis media, Sinonasal Pathology, nasal allergy, or having Eustachian tube dysfunction were excluded. Apart from routine work-up and investigations pure tone audiometry was conducted in all patients as a baseline investigation for the level of preoperative hearing. Otomicroscopy with suction clearance was also performed in all cases before the surgery to confirm the otoscopic findings, to clear any discharge and X-ray mastoid-Schuller's view of both mastoid was taken in all the cases to rule out any associated mastoid pathology and to look for the pneumatization i.e. well pneumatized, diploic or sclerotic mastoids.

Tympanoplasty was done by author in all the cases using Postaural approach and Graft take-up and Hearing improvement was assessed on Post-operative follow-up at 1 month, 3 month, 6 month and 1 year.

OBSERVATIONS: The primary aim of the study was to compare the rate of success of the different graft materials in terms of graft take-up and hearing improvement. To meet these goals, study of 75 cases with 80 ears disease (Bilateral ear involvement in 5 pt.) of Tubotympanic Chronic suppurative Otitis Media with Conductive hearing loss for whom Tympanoplasty was done by author. For the purpose of analysis, these 80 ears selected for study, were divided into groups according to the Graft material used for Tympanoplasty using Randomization method(Random allocation software 2.0).Thus in Group-I, 20 ears underwent Tympanoplasty using Temporalis Fascia, in Group-II, 20 ears underwent Tympanoplasty using Tragal Perichondrium, in Group-III, 20 ears underwent Tympanoplasty using Tragal Cartilage and in Group-IV, 20 ears underwent Tympanoplasty using Fascia Lata as graft material.

Maximum no. of ears involved were younger age group (26-35yrs.), with Male predominance i.e. 50(62.50%). It was observed that most of the tympanic perforation i.e. 73 (91.25%) were infective in origin while 7 (8.75%) cases were traumatic in origin (table 1).

Etiology	Group-I	Group-II	Group-III	Group-IV	Total	Percentage (%)
Infection	18	18	18	19	73	91.25%
Trauma	2	2	2	1	7	8.75%
Total	20	20	20	20	80	100%

Table 1: Etiology of perforation in ears included in study (n)

According to our study, the mean Pre-operative Air-bone gap (db) was found to be maximum in Subtotal perforation (31.76) followed by Large central perforation (26.85) followed by Moderate perforation (20.5).This means that, the Hearing loss was found to be proportional to size of perforation (table 2).

Size of Perforation	AC(db)	BC(db)	A-B gap(db)
Moderate CP	29.45 ± 7.59	8.95 ± 5.50	20.5 ± 5.83
Large CP	37.57 ± 5.62	10.72 ± 6.77	26.85 ± 9.07
Subtotal CP	41.76 ± 8.82	10 ± 9.89	31.76 ± 4.94
Overall	36.26 ± 7.35	9.89 ± 7.38	26.37 ± 6.61

Table 2: Pre-operative hearing loss in relation to perforation size

When success rate of Tympanic membrane closure with different graft materials was compared, Successful graft take-up rate of 85% was achieved for Temporalis Fascia (Group-I), 90% for Tragal Perichondrium (Group-II), 85% for Tragal Cartilage (Group-III) and 95% for Fascia Lata (Group-IV).However this difference in graft success was not significant statistically. Thus our result suggests that type of graft material does not influence the successful graft take-up (table 3).

Graft Material	No. of Ears	Graft Success	% Graft Success	Graft Failure	%Graft Failure	P value*
Group-I	20	17	85%	3	15%	<0.001
Group-II	20	18	90%	2	10%	<0.001
Group-III	20	17	85%	3	15%	<0.001
Group-IV	20	19	95%	1	5%	<0.001
Total	80	71	88.75%	9	11.25%	<0.001

Table 3: Graft success/failure (%) with respect to graft materials

The cases of Moderate central perforation faired well with successful graft take-up in 41/42 (97.61%), Large perforation had a successful graft take-up in 17/21 (80.95%) while in Subtotal perforation had successful graft take-up in 13/17 (76.47%) (Table 4).

Size	Graft	Success	Failure	Total	P value
Moderate	Group-I	11(91.66%)	1(8.33%)	12	
	Group-II	12(100%)	0	12	
	Group-III	11(100%)	0	11	<0.001
	Group-IV	7(100%)	0	7	
	Total	41(97.61%)	1(2.39%)	42	

Large	Group-I	4(80%)	1(20%)	5	
	Group-II	3(75%)	1(25%)	4	
	Group-III	4(66.67%)	2(33.33%)	6	<0.001
	Group-IV	6(100%)	0	6	
	Total	17(80.95%)	4(19.05%)	21	
Subtotal	Group-I	2(66.66%)	1(33.34%)	3	
	Group-II	3(75%)	1(25%)	4	
	Group-III	3(75%)	1(25%)	4	<0.001
	Group-IV	5(83.33%)	1(16.66%)	6	
	Total	13(76.47%)	4(23.53%)	17	

Table 4: Graft success with respect to size of perforation

Likewise the mean gain in hearing for Group-I was 14.15±7.99db, in Group-II was 11.25±8.5db, in Group-III was 11.85±9.79db while in Group-IV was 12.10±6.8db with an overall Gain in hearing of 12.33±7.89db.The significant association (P value=0.020<0.05) has been observed among two parameters. The mean Gain in hearing was observed maximum in Group-I (Temporalis Fascia) followed by Group-IV (Fascia Lata) (table 5).

Graft Material	Mean Pre-op ABG(db)	Mean Post-op ABG(db)	Mean Gain in Hearing (db)	P value*
Group-I	24.15±7.91	10.3±3.25	14.15±7.99	<0.001
Group-II	23.95±9.27	12.7±4.17	11.25±8.5	<0.001
Group-III	25.7±9.21	13.85±6.78	11.85±9.79	<0.001
Group-IV	24.45±8.73	12.35±3.9	12.10±6.8	<0.001
Overall	24.56±8.78	12.3±4.52	12.33±7.89	

Table 5: Improvement in Air-Bone gap in different graft materials

The Post operative complications are less and they are as follows-

Complications	Group-I	Group-II	Group-III	Group-IV	Overall
Early Graft Failure (<3 months)	1(5%)	0	1(5%)	0	2(2.5%)
Late Graft Failure (>3 months)	1(5%)	1(5%)	2(10%)	1(5%)	5(6.25%)
Retraction	1(5%)	1(5%)	0	0	2(2.5%)
Total	3(15%)	2(10%)	3(15%)	1(5%)	9(11.25%)

Table 6: Post operative complications

DISCUSSION: In the present study, we have compared the results of Temporalis fascia (group-1), Tragal perichondrium (group-2), Tragal cartilage (group-3) and Fascia lata (group-4) grafts used for the repair of tympanic membrane perforation using underlay technique. The results were compared with the other studies and discussed as follows-

There was usually no age which is free from incidence of chronic suppurative otitis media. The incidence of CSOM was found to be highest in the age group of 26-35 yrs. Accounting 33.75% in the present study which is consistent with Vineetha et al.[6] and Loy et al.[7].

The incidence of CSOM in present study was found to be higher in males (62.50%) than females (37.50%), which correlates with the Rao et al.[8] and Vijaya et al[9] study. The male predominance may be because of their more exposed way of life and probably males attend ENT OPD for treatment earlier as compared to females.

According to Rizer et al.[10] and Raj et al[11], the leading cause of chronic otitis media was infection followed by trauma, which is similar to our study showing infectious etiology in 91.25% followed by trauma in 8.75%.

The success rate of tympanic membrane closure with Temporalis fascia (group-1) was 85%, 90% for Tragal perichondrium (group-2), 85% for Tragal cartilage (group-3) and 95% for Fascia lata (group-4). Above results was not statistically significant, suggesting that the type of graft material does not influence the successful graft take-up.our results are comparable with study performed by Indorewala[12], Mohamed et al[13], Gupta et al[14], Singh et al[15] and Lin Y C[16].

According to graft success in relation to perforation size, the cases of Moderate central perforation faired well with successful graft take-up in 41/42 (97.61%), Large perforation had a successful graft take-up in 17/21 (80.95%) while in Subtotal perforation had successful graft take-up in 13/17 (76.47%). This study is similar to study done by Mohamed et al[13], Oben gamara[17] and Indorewala[12].

The mean gain in hearing of group-1 was 14.15±7.99dB, in group-2 was 11.25±8.5dB, in group-3 was 11.85±9.79dB while in group-4 was 12.10±6.8dB with an overall gain in hearing of 12.33±7.89dB. The significant association (P value = 0.020<0.05) has been observed between two parameters. Similar findings were noted in study performed by Dornhoffer[18], Indorewala[12], Singh et al[15] and Yetiser et al [19].

CONCLUSION: Though the graft success rate was maximum with Fascia Lata graft and hearing restoration was maximum with Temporalis Fascia graft, Temporalis Fascia remains the Gold standard and the most popular grafting material for its unique qualities like low metabolic rate hence less oxygen requirement, resistant to infection, graft can be obtained in ample amount from same incision with good anatomical and functional results with minimal complications. In light of comparable results, Tragal Perichondrium, Tragal Cartilage and Fascia Lata can be used for revision tympanoplasty with equally good results in cases where adequate Temporalis Fascia may not be available at the surgical site.

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