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Comparison of outcome of Cartilage Perichondrium Composite Graft with Temporalis Fascia Graft in Type I Tympanoplasty in mucosal type of Chronic Otitis Media, A Randomized Cohort study.

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ABSTRACT

Chronic Otitis Media (COM) is the major cause, responsible for deafness in India.¹ According to WHO, the Western Pacific and Southeast Asian regions contribute about 85-90% of the global burden of chronic otitis media, with India and China accounting for much of the burden. This was a Randomized Cohort of two years duration conducted after getting approval from Institutional Ethics Committee. Total 88 patients of mucosal type of Chronic Otitis Media (COM) who underwent for Type I Tympanoplasty were included in the study. They were divided into Cartilage Group (Cartilage perichondrium composite graft) and Fascia Group B (Temporalis fascia graft) with 44 patients in each group. Graft uptake rate and audiological improvement at the end of 3 months follow-up was compared between two groups. Mean Age of Cartilage group was 30.45 ± 9.85 years and that of Temporalis fascia group was 32.45 ± 9.03 years. Graft uptake rate in cartilage group, was 90.9% and that in Fascia group, it was 86.36%. Improvement in hearing (ABG closure) in Cartilage group was 10.15 ± 2.24 dB and that in temporalis fascia group was 10.83 ± 2.60 dB. The difference in graft uptake and hearing gain between two the groups after 3 months of surgery was statistically insignificant ($P < /0.05$). Overall satisfactory hearing outcome and graft uptake can be achieved with cartilage- perichondrium composite graft as good as temporalis fascia.

Keywords: Otitis Media, Hearing Loss, Tympanoplasty, Cartilage, Fascia, Pure Tone Audiometry.

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INTRODUCTION

Chronic Otitis Media (COM) is the major cause, responsible for deafness in India [1]. According to WHO, the Western Pacific and Southeast Asian regions contribute about 85-90% of the global burden of chronic otitis media, with India and China accounting for much of the burden.²In the mucosal form of COM, tympanoplasty is a procedure to eradicate the disease in the middle ear and restore the hearing mechanism. Autologous grafts such as fascia temporalis, tragal perichondrium, cartilage, fat, and fascia lata are used to repair tympanic membrane perforations. Fascia temporalis graft is the most commonly used graft material due to its healing and acoustic properties [3 – 5]. The aim of the study was to compare the outcome of Cartilage-perichondrium composite graft with Temporalis fascia in type I tympanoplasty in mucosal type of Chronic Suppurative Otitis media with respect to Graft uptake rate and hearing improvement and to compare the effect of Eustachian tube functional status on uptake of graft in the both groups.

MATERIAL AND METHODS

A hospital-based study where participants were selected based on simple random sampling technique was performed in a two-year duration in conducted in Department of Otorhinolaryngology of Tertiary Health Care Institute of Central India.

Inclusion: Patients of age group of 15-60 years of either gender requiring Type I Tympanoplasty for mucosal type of Chronic otitis Media with a dry ear for minimum of 6 (six) weeks with moderate to subtotal perforation and Pure Conductive hearing.

Exclusion: Altered ossicular status, previous surgery on same ear and those with coexisting congenital anomalies like cleft lip of palate.

Patients were divided into two groups by Random allocation software using 2 block randomization - Cartilage group and Fascia group. Written informed consent was taken from all patients before enrolling them in the study. Subjects were blinded about the graft used. Sample size was estimated for this Randomized Controlled Cohort on basis of following assumptions considering uptake of the graft as main outcome:

- Percentage of uptake in Cartilage group as 95% [12].
- Percentage of uptake in Temporalis Fascia group as 65% [12].
- α (probability of making Type 1 error) = 0.05 (2-sided)
- Power = 90%.
- Allocation ratio = 1:1. [which was to be propensity matched if failure if ratio falls below 2:3]

After due considerations, the sample size was estimated to be 42 in each group or a total of 84 patients. 88 participants were to be recruited, accounting for dropouts or loss of follow up (attrition bias). Details of all the patients including demographic data, history and clinical examination details were documented in the proforma and was blinded prior to analysis.

Otomicroscopy (Zeiss Opmi Pico) was done a day prior to surgery to see margins of the perforation, status of middle ear mucosa (MEM) and ossicular chain. Sizes of perforation were defined as follows:

1. Small perforation: Occupying the area of up to one quadrant of Tympanic Membrane (TM)
2. Medium perforation: Occupying area of size of two quadrants of TM
3. Large perforation: Occupying area of more than two quadrants of TM
4. Subtotal Perforation: Occupying all four quadrants of TM with intact annulus

Pre-operative Pure Tone Audiometry (Elkon eda Giga3 audiometer) was done by Carhart and Jerger's Technique [13] a day prior to surgery to assess the type and degree of hearing loss. Preoperative Air-Bone Gap (ABG) was calculated by taking the average of ABG at 500 Hz, 1KHz, 2KHz and 4KHz.

Eustachian Function was assessed by Toynbee's test using Impedance Audiometer (Interacoustics AT 235) [14].

Type I Tympanoplasty was performed in all patients by the experienced surgeons under Local Anaesthesia with sedation. Local anaesthetic solution consisting of 2% lignocaine with 1 in 100000 adrenaline was used for infiltration of post-aural region and in the canal. Post-aural approach was used in all patients. Tragal cartilage-perichondrium composite graft was used in Cartilage group while temporal fascia was used as a graft material in Fascia group patients.

In cartilage group patients, tragal cartilage perichondrium composite graft was harvested by giving incision over the medial side of tragus, leaving a 2mm strip of cartilage in the dome of the tragus for cosmesis [15]. To maximize the length of harvested cartilage, an inferior cut was made as low as possible (typically 15 mm length and 10 mm in width in children and somewhat larger in adults). Perichondrium from the side away from the external auditory canal was dissected leaving the thinner perichondrium on the reverse side. A flap perichondrium was produced posteriorly that will eventually drape over the posterior canal wall. Part of cartilage at the periphery was removed resulting into a large piece of perichondrium with a round cartilage disc in the middle in the shape of a fried egg. In our study, a narrow triangle was removed from the centre of the cartilage island with base towards periphery for accommodation of handle of malleus [15]. (Fig 2).

Patients received a course of suitable broad-spectrum antibiotics and decongestants for 2 weeks. Those patients in both the groups were followed up in ENT OPD postoperatively on 7th, 15th day and 1st, 3rd and 6th month. Final assessment of Tympanic Membrane by Otomicroscopy and hearing by PTA were done at the end of 3 months postoperatively. An intact mobile Tympanic Membrane was considered as a successful Graft uptake. The presence of residual perforation or medialization of graft was considered as a failure of graft. Postoperative Air-Bone Gap (ABG) was calculated by taking the average of ABG at 500 Hz, 1 KHz, 2 KHz and 4 KHz. ABG Closure was calculated by subtracting Post-operative A-B Gap from Preoperative A-B Gap. Audiological improvement was considered when there was improvement in patient's hearing in speech frequencies (500, 1000 & 2000Hz) in terms of ABG closure of more than or equal to 10 dB.

Data was analysed using SPSS version 27.0. Two groups were compared for categorical variables using Pearson's Chi-square test and for continuous parametric variables, Student t-test was used. 2 sample test of proportion was used for comparison of Graft uptake in both groups according to Eustachian tube functional status. Statistical significance was evaluated at 5% level ($p < 0.05$).

RESULTS

Total 88 patients were included in this study with 44 patients each in cartilage group and fascia group. As shown in Table 1, Mean age of cartilage group was 30.45 ± 9.85 years and that of Fascia group was 32.45 ± 9.03 years. The overall age distribution of patients in two treatment groups was statistically insignificant ($P = 0.68$) using Pearson's Chi-square test. 21- 30 years (47.72%) was the commonest age group involved in Cartilage Group while it was 31-40 years age group (38.63%) in Temporalis Fascia Group. In Cartilage group, there were 16 (36.36%) males and 28 (63.64%) females with male to female ratio of 1:1.75 and in Fascia group, there were 15 (34.09%) males and 29 (65.91%) females with male to female ratio of 1:1.93. The difference in distribution of gender between two groups was statistically insignificant ($p = 0.82$) using Pearson's Chi-square test. In the Cartilage group, there were 38 (86.36%) cases with unilateral involvement (Right ear- 31.82% and Left ear- 54.54%) and 6 (13.64%) had bilateral involvement. In the Fascia group, 36 (81.8%) had unilateral disease (Right ear - 38.6% and Left ear- 43.2%) while 8 (18.18%) had bilateral disease. Both the groups had maximum number of patients with left ear involvement (Table 1).

Graft uptake rate in Cartilage group was 90.90% versus 86.36% in Fascia group showing no statistically significant difference ($p = 0.50$, Chi-square Test). (Table 2) Medialization of graft was observed in 1 patient and small residual perforation in 3 patients in Cartilage group. While in Fascia group, 3 patients had medialization of graft, 2 had small residual perforation and 1 had complete failure of graft after 3 months follow up (Table 3).

As shown in Table 4, Graft uptake rate as per size of perforation in two treatment groups was studied. In Cartilage group, the success rate was 100% in patients with Moderate Central Perforation (CP), while in large CP group, the success rate was 91.66%. Subtotal CP had 71.4% graft uptake rate. The overall success rate was 90.9%. In fascia group, overall success rate was 86.36%. The difference in the success rates of graft uptake as per size of perforation in two groups was statistically insignificant with p value of 0.761 (p>0.05) using Fisher’s exact test.

Table 5 shows Comparison of Status of graft uptake in both groups according to Eustachian tube functional status. In Cartilage group, out of 30 cases having normal Eustachian tube function, 29 cases (93.33%) showed successful uptake. Nearly similar results were observed in Fascia group. Out of 33 cases with normal Eustachian tube function in fascia group, 31 cases (93.93%) had success in terms of uptake. 90.9% (10 out of 11) cases with Eustachian tube dysfunction in Cartilage group had successful uptake, whereas it was 66.67% in Fascia group. In those with impaired Eustachian tube function successful graft take up was 33.33% in Cartilage group but fascia group had failure of graft in all. Since the sample size of patients with Impaired eustachian tube was small, the categories of Dysfunction and Impaired ET were clubbed into one group and 2 sample test of proportion was applied to the data. This gave a p-value of 0.34 which was statistically insignificant.

As shown in Table 5, in the Cartilage group, the mean preoperative Air-Bone Gap (ABG) was 35.98 ± 6.92 dB which improved 3 months postoperatively to 25.83 ± 6.85 dB and there was a significant difference statistically (P<0.001). The values of pre- and postoperative ABG in the Fascia group (38.41 ± 6.82 dB and 27.58 ± 7.05 dB) also represented a significant improvement in hearing (P<0.001). Mean Air Bone Gap Closure (ABGC) in Cartilage group was 10.15±2.24 dB and that in Fascia group was 10.8±2.60 dB, showing no statistically significant difference (p=0.19) between the two groups.

Table 1: Distribution of patients in Endoscopic and Microscopic Tympanoplasty groups according to demographic characters and clinical presentation.

Variables		Cartilage group (n=44)	Fascia Group (n=44)	P value*
Gender, N (%)	Male	16 (36.36%)	15 (34.09%)	-
	Female	28 (63.64%)	29 (65.91%)	
	Male: Female	1:1.75	1:1.93.	
Age in Years (Mean ± SD)		30.45 ± 9.85	32.45 ± 9.03	0.683
Laterality of the disease	Right	14 (31.82%)	17 (38.60%)	-
	Left	24 (54.54%)	19 (43.20%)	
	Bilateral	6 (13.64%)	8 (18.20%)	
Size of Perforation	Moderate	13 (29.54%)	16 (36.40%)	0.7171
	Large	24 (54.55%)	23 (52.30%)	
	Subtotal	7 (15.91%)	5 (11.3%)	

SD- Standard Deviation, * Pearson’s Chi- square Test used, p value< 0.05- statistically significant

Table 2: Distribution of patients according to status of graft uptake after 3 months post-operatively

Graft uptake	Treatment groups		P value*
	Cartilage group (n= 44)	Fascia group (n= 44)	
	N (%)	N (%)	
Success	40 (90.9%)	38 (86.36%)	0.5017
Failure	4 (9.1%)	6 (13.63%)	
Total	44 (100%)	44 (100%)	

* p value using Pearson’s chi-square test- 0.5017 (P > 0.05).

Table 3: Distribution of patients as per size of perforation & status of graft at end of 3 months post-operatively.

Size of perforation	Treatment Groups			
	Cartilage Group, (n=44)		Fascia Group, (n=44)	
	Success N (%)	Failure N (%)	Success N (%)	Failure N (%)
Moderate CP	13 (100%)	00	15 (93.75%)	1 (6.25%)
Large CP	22 (91.66%)	2 (8.33%)	20 (86.96%)	3 (13.04%)
Subtotal CP	5 (71.43%)	2 (28.57%)	3 (60%)	2 (40%)
Total	40 (90.91%)	4 (9.1%)	38 (86.36%)	6 (13.64%)

*p value=0.761 (P>0.05) using Fisher's exact test

Table 4: Comparison of Air Bone Gap (ABG) between pre- and post-operatively in individual groupmind comparison of Mean Air Bone Gap closure between the two groups.

Treatment Group	ABG: Mean ± SD (dB)		Mean ABGC	P-value*
	Pre-operative	Post-operative		
Cartilage group (n=44)	35.98±6.92	25.83±6.85	10.15±2.24	<0.00001
Fascia group (n=44)	38.41±6.82	27.58±7.056	10.83±2.60	<0.00001
Comparison of Mean ABGC Between Two groups		P value#	0.1923	-

*p value < 0.05 statistically significant, * Paired t-test, # Independent t-Test

Table 5: Distribution of patients according to post-operative ABG closure after 6 months in two groups

Hearing Improvement	Treatment groups	
	Cartilage group (n=44)	Fascia group (n=44)
	N (%)	N (%)
Improvement (ABGC ≥ 10dB)	29 (65.9%)	36 (81.8%)
No Improvement (ABGC<10dB)	15 (34.1%)	8 (18.2%)
Total	44 (100%)	44 (100%)

*p value of 0.08 (P > 0.05) using Pearson's chi-square test.



Figure 1: Tragal Cartilage-Perichondrium composite island graft with a hook for malleus

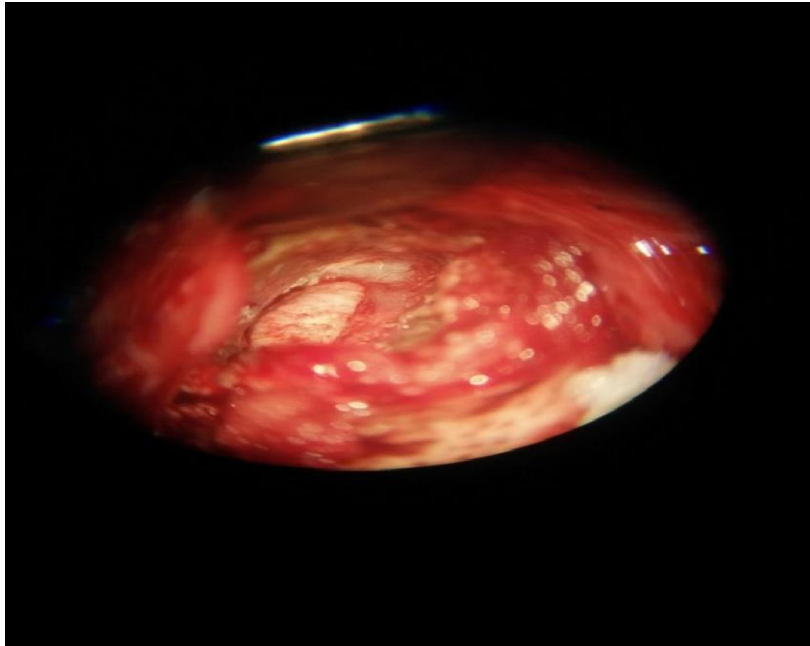


Figure 2: Cartilage Graft placed by Underlay Technique

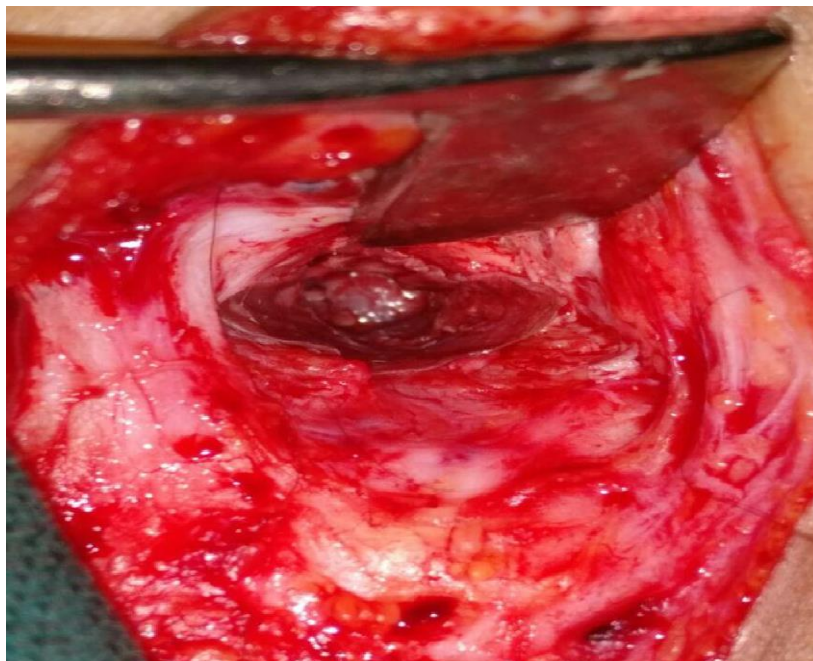


Figure 3: Temporalis Fascia graft placed by Underlay technique

DISCUSSION

Tympanoplasty is the main surgical treatment for the mucosal form of chronic otitis media. In patients with chronic ET dysfunction, the tympanic membrane or neo-tympanic membrane retracts and adheres to the promontory, leading to atelectasis and surgical failure. In such cases, cartilage perichondrium leads to better results than temporalis fascia or perichondrium alone because it is better able to withstand middle ear pressure fluctuations and infection. Postoperative retraction pocket formation is less common with cartilage grafts. Various techniques for cartilage tympanoplasty have been described in the literature, including cartilage-perichondrium composite grafts, butterfly techniques, palisade cartilage tympanoplasty, and cartilage cubes [16].

In our study, mean age of cartilage group was 30.45 years and that of temporalis fascia was 32.45 years. Females outnumbered males with male to female ratio in cartilage group was 1:1.75 and that in temporalis fascia it was 1: 1.93. Unilateral disease was more common than bilateral. 38 (86.36%) patients of cartilage group and 36 (81.8%) patients of temporalis fascia group had unilateral disease. Left ear was most commonly affected. There was no statistically significant difference between these two groups related to these parameters. Guler I et al found no statistically significant differences between Cartilage and Fascia groups in terms of age (66.8 ± 2.9 years and 65.6 ± 1.4 , respectively; $p= 0.108$), gender (Male/Female, 15/16 and 16/26 respectively, $p= 0.379$), operated side (left/Right- 21/10 and 32/10 respectively, $p= 0.424$) [17]. In Gozeler et al study, similar was the finding with no statistically significant difference between Cartilage and Fascia groups in terms of age (29.1 ± 8.2 years and 31.9 ± 10.0 years respectively, $p= .10$), gender (M/F = 24/35 and 24/30 respectively, $p=0 .69$) [18]. Our findings were consistent with those studies and also with the studies by Khalilulah et al [2], Bhattacharya et al [19] and Shergill et al [20].

In the present RCT, at the end of 3 months, successful graft uptake in cartilage group was 90.9% patients better as compared to fascia group (86.36%.) but the difference between the two was statistically insignificant ($P=0.50$). Medialization of graft was found in 1 patient of the cartilage group as compared to 3 patients of fascia group. Guler et al found successful graft uptake 93.5% (29 patients) for the Cartilage group versus 76.2% (32 patients) for the Fascia group. The success rate for the cartilage group was significantly higher than that for the fascia group ($P = 0.048$) [17]. In Gozeler et al study, tympanic membrane perforation closure success rate in the Cartilage group was higher than those in the Fascia group (91.0% vs 83.3%; $P=0.046$) [18]. In Jain et al study, at 1 year follow up, the graft take up rate for island cartilage and temporalis fascia graft were found to be 97.1% and 82.9% respectively, which was found to be statistically significant ($p < 0.05$). They reported retraction of graft in 2 patients of Fascia group in their follow-up period but none in the Cartilage group.²¹ In a study by Sood et al [9], at the end of 2 months, graft uptake was 95% with tragal cartilage with perichondrium and 90% with temporalis fascia. This difference was not statistically significant. In a study by Rout et al [3], graft take-up rate in temporalis fascia group was 82.67% and in tragal cartilage group, it was 95.34%. Mohanty et al compared the clinical outcomes of endoscopic cartilage versus temporalis fascia grafting in anterior quadrant perforations and they reported an overall success rate as 91.9% in cartilage and 79% in fascia groups. The changes in ABG were similar in both groups. After 1-year follow-up, they observed medialization of graft in 5 patients in the fascia group but no patients in the cartilage group had medialization or lateralization. They suggested cartilage perichondrium technique as an effective technique for anterior quadrant perforations [22].

In the present study, in cartilage group, the pre-operative mean ABG was 35.98 ± 6.92 dB, which improved to 25.83 ± 6.85 dB post-operatively which was statistically significant ($P < 0.0001$). Further, in temporalis fascia group, the mean ABG before surgery was 38.41 ± 6.83 dB, while post-operative mean ABG was 27.58 ± 7.05 dB, showing statistically significant reduction ($P < 0.0001$) using paired t-test. Hearing gain (ABG closure) in Cartilage group was 10.15 ± 2.24 dB and that in temporalis Fascia group was 10.83 ± 2.60 dB. The difference in hearing gain between two groups was statistically insignificant ($P > 0.05$). In Jain et al study, the average air-bone gap closure was found to be 19 ± 10.9 dB for island cartilage graft and 17.2 ± 8 dB for temporalis fascia and the difference was not statistically significant ($p > 0.05$). Guler et al found the mean hearing gain of 8.9 ± 6.1 dB and 12.5 ± 7.6 in the cartilage and fascia group respectively. The mean hearing gain was significantly higher in the fascia group than in the cartilage group ($P = 0.028$) [17]. In Gozeler et al study, Comparison of pre- and postoperative audiometry revealed a significant improvement in ABG in both groups, with no significant difference between two groups [18]. In the Cartilage group, preoperative ABG was 19.5 ± 5 dB and postoperative ABG was 10.8 ± 4.8 dB. In the fascia group, the corresponding values were 20.7 ± 5.4 and 11.5 ± 5.4 dB, respectively (p value $< .05$) [18]. Venkatesan D et al observed mean ABG closure of 11.5 ± 5 in cartilage group vs 13.39 ± 7.44 in fascia group. This difference is also not statistically significant (p value 0.253) [23]. In Shergill GS et al study, preoperative ABG in tragal cartilage group was 29.11 ± 9.9 dB which improved postoperatively to 18.96 ± 9.1 dB. Preoperative ABG in temporalis fascia group was 32 ± 11.1 dB which improved postoperatively to 20.97 ± 8.9 dB. Mean ABG closure in tragal cartilage group was $10.14 \text{ dB} \pm 7.5 \text{ dB}$ and that in temporal fascia graft group, it was $11.02 \text{ dB} \pm 9.9 \text{ dB}$. The difference in the hearing improvement between two groups was statistically significant (p value < 0.05) [20]. Ciger et al compared these 2 graft materials in their prospective, randomized study and they found similar hearing outcomes in both techniques. Graft

success rate at the first year was 85.1% in the Fascia group and 97.7% in the Cartilage group and this difference was statistically significant [24-25].

CONCLUSION

Overall satisfactory hearing outcome and graft uptake can be achieved with cartilage-perichondrium composite graft as good as temporalis fascia.

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