Journal of Cardiovascular Disease Research

ISSN: 0975-3583,0976-2833 VOL15, ISSUE 08, 2024

Original Research Article

Prospective Comparative Study on Tympanoplasty Type-1 Graft Uptake Between Tragal Cartilage Perichondrium and Temporalis Fascia

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Received: 06-06-2024 / Revised: 16-06-2024 / Accepted: 24-07-2024

ABSTRACT

Background
Chronic Otitis Media (COM) is one of the leading causes of hearing loss in the world. Tympanoplasty is the surgical treatment to repair the defective tympanic membrane in such patients.

Aim
To compare the healing and graft uptake using temporalis fascia versus cartilage perichondrium grafts in tympanoplasty type-1.

Method
A prospective randomized comparative cohort trial was conducted in the Department of Otorhinolaryngology at a Private Medical College in South India in the year 2020. This study compared the effect of two graft materials, tragal cartilage perichondrium and temporalis fascia, in tympanoplasty and evaluated the post-operative healing, among 60 patients randomized into 2 groups.

Results
93% cases belonging to the cartilage perichondrium graft group had formation of neotympanum compared to only 53% cases in Temporalis fascia group. Statistically significant difference between the two groups in terms of formation of neotympanum suggests cartilage perichondrium was better in the aspect of healing and graft uptake.

Conclusion
Results of this study conclude that tragal cartilage perichondrium is significantly better than temporalis fascia in terms of graft uptake in cases of Type I Tympanoplasty.

Keywords: Tympanoplasty Grafts, Tragal Perichondrium, Temporalis Fascia, Graft uptake**.**

INTRODUCTION

Chronic Otitis Media (COM, is defined as a long standing irreversible inflammation of mucoperiostial lining of the middle ear cleft resulting in changes in the tympanic membrane.[1] It is prevalent in about 65 to 330 million people around the world with 60% of them suffering from significant hearing loss.[2] Tympanoplasty is the surgical procedure which includes the manipulation of the tympanic membrane and eradication of disease from the middle ear. The ideal grafting material used for tympanoplasty should meet certain criteria namely, low rejection rate, sufficient quantity, good tensile strength, conductive properties similar to that of tympanic membrane and easy availability.[3] Numerous materials have been tried as a grafting material

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namely homograft, alloplastic, and autologous material but none withstanding the test of time except the autologous materials. It includes skin, fascia lata, temporalis fascia, vein and perichondrium.

In this study, comparison of graft materials done between temporalis fascia and tragal cartilage perichondrium. advantage of using Temporalis fascia is that it does not require an additional surgical incision for the harvest of the material and better functional outcome in terms of hearing. However the poor dimensional stability of this material has resulted in residual perforations in large and sub-total tympanic membrane perforations.

A composite graft combining cartilage with perichondrium would theoretically work well, being tougher and easily nourished. The incorporated cartilage would give it the necessary stiffness and mechanical stability to avoid retraction. Also, it has a low metabolic rate and good acceptance in the middle ear.

AIM

The aim of this study is to compare the healing and graft uptake using temporalis fascia versus cartilage perichondrium in tympanoplasty.

MATERIALS AND METHODS

This prospective randomised comparative cohort trial was conducted in the Department of Otorhinolaryngology at a Private Medical College in the year 2020. The study compared the effect of two graft materials, tragal cartilage perichondrium and temporalis fascia, in tympanoplasty and evaluated the post-operative healing. All patients were explained about the study and a written informed consent was obtained prior to participation. A total number of 60 patients randomised into 2 groups were included in this study (n=60). The patients included in the study are healthy male and female above 18 years of age with mucosal type of ear disease and pure conductive hearing loss. Patients with squamous type ear disease, bilateral ear disease, ossicular dysfunction & external ear pathology, sensorineural hearing loss and mixed hearing loss, previous ear surgery and intracranial / extracranial complications of COM are excluded from the study.

Patients diagnosed with COM – mucosal disease were randomly allotted to one of the 2 groups – Group A (Cartilage perichondrium graft) and Group B (Temporalis Fascia graft). All patients underwent pre-operative Otomicroscopic Examination and Pure Tone Audiometry. A power calculation showed that a sample size of 60 patients would achieve a power of 90%. Patients who met the inclusion criteria were subjected to medical fitness for General Anesthesia (GA).

All surgeries were done under GA. A post auricular incision was placed and Type I tympanoplasty performed. Then harvesting of the graft material was done. For a tragal perichondrial graft, an incision made over the inner surface of the tragus, soft tissues dissected and tragal cartilage perichondrium were identified and harvested. The graft material was thinned and dried so that the cartilage and perichondrium were attached at one end. The underlay placement of the graft was done such that cartilage part cover the perforation and perichondrium part stabilised the graft as it came under the tympanomeatal flap. The tragal wound was sutured. Mastoid dressing was done

The temporalis fascia graft was harvested by placing an incision over post-aural region, soft tissues dissected and temporalis fascia was identified and harvested. The graft material was teased and dried.

Graft material was placed by underlay technique. Medicated gelfoam was placed adequately under the graft to prevent medialisation of the graft material. All patients recovered uneventfully. Patients were on parental antibiotics and anti-inflammatory for 3 days, followed by oral antibiotics and anti -inflammatory for 4 days. All the patients were on similar post-operative care and diet. Surgical wound was cleansed and dressing changed everyday. Sutures were removed on 7^{th} post-operativeday.

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All patients were subjected to otomicroscopic examination at the end of 1 month post-operatively for analysis of neo-tympanum. Statistical analysis was done using the Paired and unpaired t-tests.

RESULTS

60 patients with dry central perforation were included in this study. 30 patients were allocated to Group A and 30 to Group B randomly using numbered lots. 57 patients complied with the study protocol, tolerated the surgical procedures and completed the follow-up. 3 candidates of Group A dropped-out of the study after undergoing surgery. Repair of the tympanic membrane in patients in Group A was done with Tragal cartilage perichondrium (n=27) and in Group B with Temporalis fascia (n=30). Of the 27 patients in group A, 10 were males and 17 were females, whereas there were 6 males and 24 females in Group B (Chart 1). All the patients underwent Type I tympanoplasty (n=57).

The parameter analysed in the study was the formation of neotympanum using otoscopy,

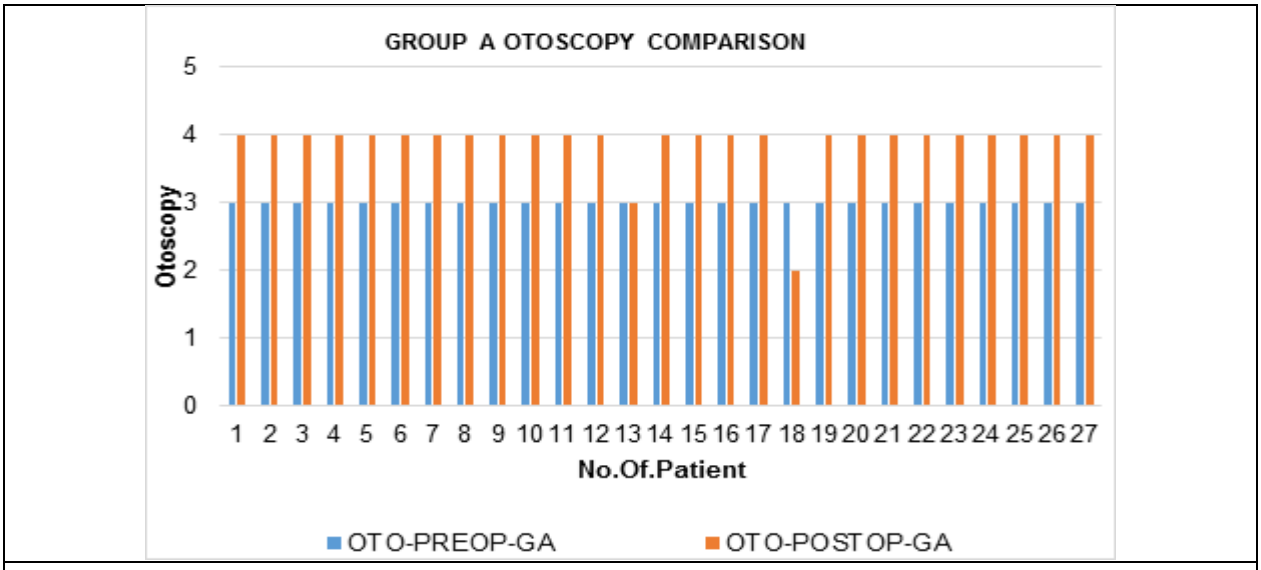
At the end of 1 month post-operatively, formation of neotympanum was examined using otoscope. In Group A, 25 out of 27 (93%) patients had intact neotympanum, which is indicated by a score of 4. 1 patient had residual central perforation and 1 patient had otomycosis, which are marked by scores 3 and 2 respectively (Graph 1).In Group B, 16 out of 30 (53%) patients had intact neotympanum with score 4, 13 patients had residual central perforation marked by a score of 3 and 1 patient had otomycosis with pulsatile discharge with score 1(Graph 2).

There was statistical significance in the pre-operative and post-operative Otoscopic findings in both the groups (Table 1)

Failure rate

In Group A (Cartilage perichondrium), 1 patient had residual Central perforation (3.7%) whereas in Group B (Fascia), 13 patients had residual Central perforation (43.33%).

Post-operatively, in Group A (Cartilage perichondrium), 1 patient had otomycosis (3.7%) and in Group B (Fascia), 1 patient had otomycosis with pulsatile discharge (3.33%). These patients were managed conservatively and followed up for another 3 months. The neotympanum formation levels were satisfactory.



Graph 1: Comparison of pre-operative and post-operative otoscopy findings of patients in Group A (Tragal cartilage perichondrium)

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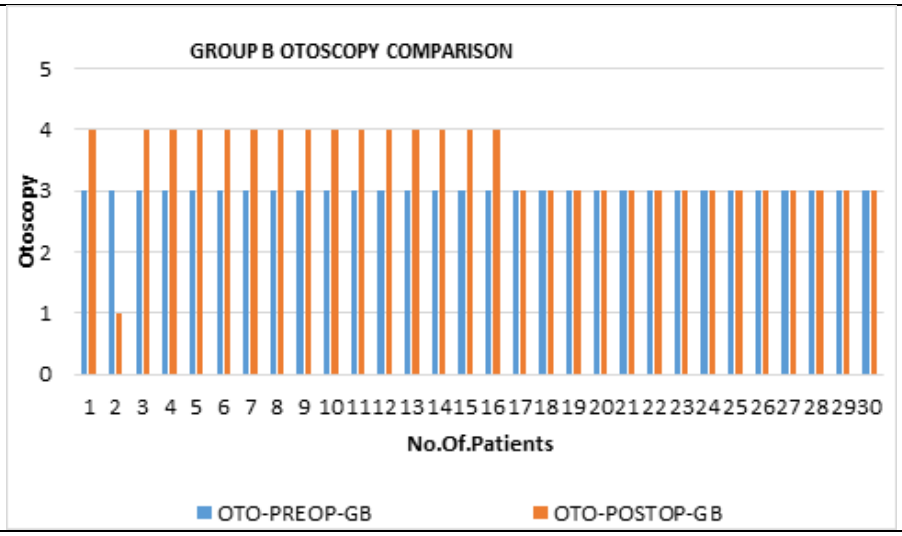
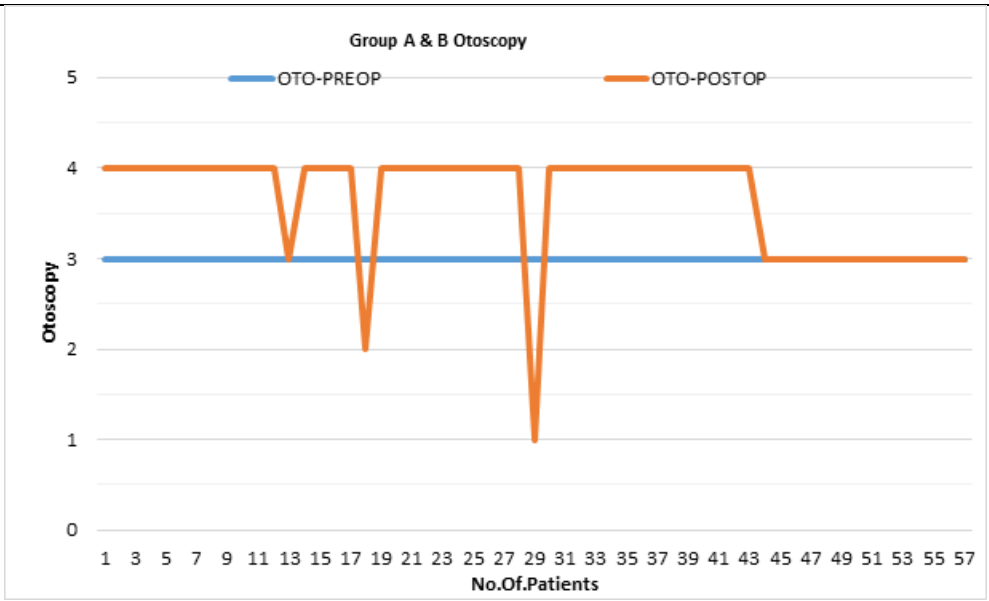


Graph 2: Comparison of pre-operative and post-operative otoscopy findings of patients in Group B (Temporalis Fascia Graft)



Graph 3: Comparison of pre-operative and post-operative otoscopy findings of patients in Group A (Tragal cartilage perichondrium)

Paired Samples Statistics					
		Mean	N	Std. Deviation	Std. Error Mean
	PREOP_OTO	3.00	57	0.000	0.000
	POSTOP_OTO	3.65	57	.612	.081

Table 1

Paired Samples Test								
	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
PREOP_OTO - POSTOP_OTO	-.649	.612	.081	-.812	-.487	-8.006	56	.000

Table 2

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Group Statistics					
VAR00002		N	Mean	Std. Deviation	Std. Error Mean
OTO_POSTOP	1.00	27	3.8889	.42366	.08153
	2.00	30	3.4333	.67891	.12395

Table 3

Independent Samples Test										
		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
OTO_POSTOP	Equal variances assumed	14.028	.000	2.999	55	.004	.45556	.15190	.15115	.75997
	Equal variances not assumed			3.071	49.242	.003	.45556	.14836	.15745	.75367

Table 4

DISCUSSION

Tympanoplasty refers to reconstruction of the tympanic membrane with or without reconstruction of the ossicular chain. The primary goals of tympanoplsty are: (1) Repair of defect so as to close the tympanic cavity. Thus preventing recurrent middle ear infection. (2) Neotympanum should be able to resist middle ear pressure changes in eustachian tube dysfunction where the perforation is large. (3) The acoustic properties of the neotympanum should be similar to a healthy tympanic membrane.[4]

The parameters assessed in the study were graft uptake indicated by formation of neotympanum. The results of this study showed that 93% of cases belonging to the cartilage perichondrium graft group had formation of neotympanum and only 53% of cases in Temporalis fascia showed formation of neotympanum. There was a statistically significant difference between the two groups in terms of formation of neotympanum suggesting cartilage perichondrium was better in this aspect. The results of our study support other studies which show cartilage grafts to be better when compared to temporalis fascia. The success rate of cartilage grafts is reported up to 100%,[5-11] as opposed to 93% in our study. The drop in the success rate was due to failure of the graft in one of the cases, which may be attributed to the inadequate amount of the graft harvested.

The reasons for better uptake of cartilage perichondrium composite graft could be because its nourishment is by diffusion and not by neovascularization,[12] it can withstand negative pressure of the middle ear cavity due to its thickness and rigidity,[13] its low metabolic rate and ability to resist prolonged absence of neo-vascularisation providing better resistance against infection[14,15] and better incorporation with the remnant tympanic membrane.[16] The incorporation of the perichondrium with the cartilage allows for better nourishment of the graft and it is recommended to leave the perichondrium on atleast one of the sides of the cartilage.[4] In our study, we have retained the perichondrium on one side of the graft. One other way of retaining

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perichondrium is by employing the island perichondrium technique. Reports show better outcome regarding closure of perforation with perichondrium/cartilage island than with either temporalis fascia or cartilage palisades.[17] Cavaliere et al,[18] showed that cartilage perichondrium used with cartilage shield tympanoplasty had a graft take of 100% in primary tympanoplasties. This is also supported by other studies in literature.[19-23]

The graft uptake rate for temporalis fascia ranges between 86 and 97%.[5,24-26] whereas it is 53% in our study. The reasons for more failure to be seen with the temporalis fascia are poor adaptation of the graft, shrinkage and flexibility. Temporalis fascia may suffer vascularisation and may undergo shrinkage or atrophy. The flexible nature may not allow the graft to resist the negative pressure that can develop within the middle ear cavity. Temporalis fascia and perichondrium alone often fails as graft material for tympanic membrane reconstructions because of their low mechanical stability and tendency to atrophy over the years.[27,28]

To avoid the flexible temporalis graft giving up to the negative pressure, it is advisable to use a supporting material on the medial aspect of the graft. When the graft is supported medially only by soft material such as gelfoam (abgel), failure is seen in large number of cases. Authors have shown that temporalis fascia supported by cartilage on the medial aspect can be rigid and can resist retraction.[29,30]

CONCLUSION

This study shows that the graft uptake with tragal cartilage perichondrium is good. The argument regarding the thickness of the cartilage impairing sound conduction is proved wrong as we did not do thinning of the cartilage perichondrium graft in any of our cases. The results of this study conclude that tragal cartilage perichondrium is significantly better than temporalis fascia in terms of graft uptake in cases of Type I Tympanoplasty.

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