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Research Article

HEARING IMPROVEMENT FOLLOWING TYMPANOPLASTY USING TEMPORALIS FASCIA AND TRAGAL PERICHONDRIUM – A COMPARATIVE STUDY IN INDIAN POPULATION

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A R T I C L E I N F O

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A B S T R A C T

Introduction: Studies comparing temporalis fascia & tragal perichondrium for repairing tympanic membrane perforation and hearing improvement on Indian population are only very few. This prompted us to do a comparative study.
Aims and objectives: To assess and compare the hearing improvement following tympanoplasty, using temporalis fascia and tragal perichondrium.
Materials and Methods: The present study using either temporalis fascia or tragal perichondrium as a graft material in tympanoplasty is a prospective comparative study, where the Air-Bone gap [AB] gain following surgery in both the groups was assessed and compared.
Observation and Results: On comparing the mean postoperative AB gain in both the groups using unpaired t-test and Fischer exact test, the p value is < 0.05 which is statistically not significant, which implies both the groups give equal hearing improvement following surgery.
Conclusion: Both tragal perichondrium and temporalis fascia provide good autograft material and achieve nearly equal hearing restoration.

INTRODUCTION

Hearing is one of the special senses which help humans to communicate with their fellows through speech. Verbal communication is an effective method. Deafness is a disability that hinders a person's social integration. Chronic suppurative otitis media is one of the important cause of deafness in developing countries like India(1) due to lack of adequate nutrition, poor socioeconomic status, lack of health awareness, and unhygienic personal habits (2). Wullstein, in 1953, introduced the terminology of tympanoplasty to describe the surgery for middle ear hearing mechanism reconstruction (with or without tympanic membrane grafting) impaired by chronic middle ear disease. There is in-growth of connective tissue edges and upon which the epithelial tissue migrates and closes the perforation of the eardrum. Connective tissue grafts of mesodermal origin like vein, perichondrium or fascia, proves better compared to other grafts. Temporalis fascia as a grafting material was first considered by Heerman, while Storrs employed it successfully. Goodhill considered the idea of grafting tragal cartilage and perichondrium (3). A good graft used for tympanic membrane closure should have few basic criteria such as minimal graft rejection, enough quantity, good tensile strength, conductive properties same as of tympanic membrane and ready availability.

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Temporalis fascia graft, Perichondrial graft, Fascia lata graft, Tragal cartilage graft, Porcine dura, Calf jugular vein, Cadaveric dura, Cadaveric tympanic membrane were the various graft materials used.

Temporalis fascia graft is the most preferred one for repairing tympanic membrane (TM) perforation, because it is easily available in the same surgical site with the same thickness as TM and it also has a low basal metabolic rate. The Tragal perichondrium is also available in the same surgical site, and it has good stability.

There are only a few studies on Indian population comparing the two materials for the repair of tympanic membrane perforation and hearing improvement. It has prompted us to do a comparative study between these two materials.

Aims and objectives

To assess and compare the hearing improvement following tympanoplasty, using temporalis fascia and tragal perichondrium

MATERIALS AND METHODS

The present study of comparing temporalis fascia and tragal perichondrium as a graft in tympanoplasty is a prospective comparative study carried out in a Tertiary Care Hospital after obtaining institutional ethical clearance and informed consent.

Study duration: 2013 - 2015
Sample Size: 100
Ethical Committee Approval obtained- {August 2013}

Inclusion Criteria

All patients aged 15 to 45 years of age with tubotympanic Chronic Suppurative otitis Media [CSOM]

The ear should be dry minimum for six weeks.

Patient willing to give written informed consent for surgery.

Exclusion Criteria

Revision surgery cases
Diabetes.
Congenital hearing disorder
Patients with superimposed otomycosis
Patients with active discharge
Patients with sensorineural and mixed hearing loss
Patients with the history of ear discharge and decreased hearing were screened. Detailed history taking and clinical examination were done to see the type of perforation, presence of discharge in the middle ear, integrity of the ossicular chain, granulation, polyps, etc.

Blood and urine examination were done. Hearing assessment was done by tuning fork tests and Pure tone audiometry. X-ray Mastoids both sides was taken

Patients were divided into 2 groups by random assignment.

Group A – Patient's undergoing tympanoplasty with Temporalis fascia graft

Group B – Patient's undergoing tympanoplasty with Tragal perichondrium graft

Appropriate antibiotics, along with antihistaminic, analgesics and antipyretics were given. Tympanoplasty type I (underlay) is the surgical technique used in all patients either by the post aural or end aural approach. Surgery was performed either under general anesthesia or local anesthesia. A separate incision was made for harvesting tragal perichondrium. The patients were followed up after surgery at regular intervals. Pure tone audiometry was done 1 month, 3 months and 6 months postoperatively.

Hearing improvement in each group is assessed using paired't" test for comparing Pre operative AB gap with their corresponding Post operative AB gap. Post operative AB gap of both the groups was compared using the unpaired t-test. AB gain in both groups was compared using unpaired t-test.

Statistical analysis: Comparison of the qualitative variables was analyzed by Fischer exact test. Comparison of quantitative variables was analyzed by paired and un paired t-test according to distribution. A p value of 0.05 was taken as the level of significance. Results of continuous measurement were presented as Mean +/- SD (min-max) and results on categorical measurements were presented in number (%). Data analysis was performed using the EZR software using R version 3.6.1 (2019-07-05).

OBSERVATION AND RESULTS

Mean age of group A was 28.26 yrs& Group B was 29.22 yrs. In Group A there were 28 male (56%) patients and 22 female (24%) patients. In Group B there were 27 male (54%) & 23 female (46%) patients.
Distribution based on size of perforation among 50 patients in Group A is Large 12 (24%), Moderate 31 (62%) & Small 5 (10%) perforation. Most of the patients are identified to have only unilateral disease. Cases operated under General anaesthesia in Group A was 22 (44%) & in Group B was 25 (56%). 28 (56%) patients in Group A and 22 (44%) patients in Group B underwent the Surgery under local anaesthesia. Most of the patients were operated through post aural approach. Graft up take rate in both groups was found to be equal. (Table 1)

Table 1 Descriptive details

Characteristics	Group A	Group B	P value
Mean age (years)	28.26	29.22	0.488
Sex			
Male	28(56%)	27(54%)	
Female	22(44%)	23 (46%)	0.8407
Type of Perforation			
Large	12 (24%)	11 (22%)	0.834
Moderate	31 (62%)	34 (68%)	
Small	07 (14%)	05 (10%)	
Involvement			
Unilateral	15 (30%)	12 (24%)	0.656
Bilateral	35 (70%)	38 (76%)	
Type of Anaesthesia			
General	22 (44%)	28 (56%)	0.161
Local	28 (56%)	22 (44%)	
Route of Surgery			
Endomeatal	04 (8%)	07 (14%)	0.883
Postaural	46 (92%)	43 (86%)	
Graft Take Up			
Yes	44 (88%)	44 (88%)	1
No	06 (12%)	06 (12%)	

In the distribution of pre operative air-bone gap between the two groups (total 100 patients), out of 50 patients from Group A 3 (6%) in 11 to 20 dB (Pre-Op. ABG) 25 (50%) patients in 21 to 30 dB (Pre-Op.ABG) & 22 (44%) patients in 31 to 40 dB (Pre-Op.ABG) & out of 50 patients from Group B Pre-Op air Bone Gap dB between 1 to 10 dB 1 (2%) patients, in 11 to 20 dB = 5 (10%) patients, 21 to 30 dB – 27 (54%) patients & 31 to 40 dB = 17 (34%) patients. (Figure1).

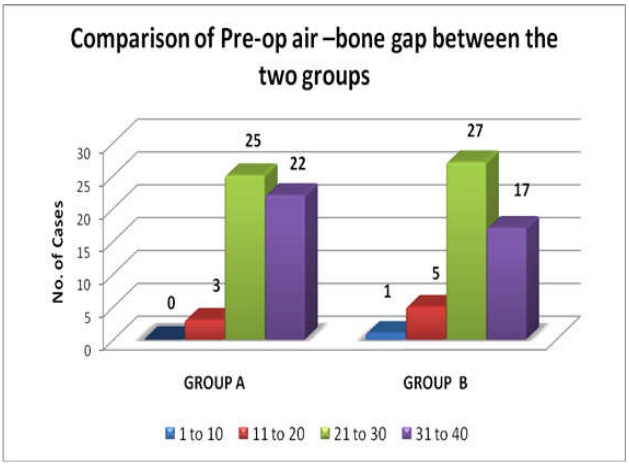

Figure 1 Comparison of Mean Pre operative AB Gap between two Groups

In the distribution of Post operative Air – Bone gap between the two groups (total 100 patients), out of 50 patients from Group A Post op- air- Bone gap in dB between 0 dB = 00, 1 to 10 dB =10 (20%) patients, 11 to 20 dB = 31 (62%), 21 to 30 dB = 09 (15%) patients & out of 50 patients from Group B post-op -air-Bone gap in dB between 0 dB = 1 (2%) patients,1

to 10 = 15 (30%), 11 to 20 dB = 23 (46%) patients, 21 to 30 dB = 11 (22%) patients, in both Groups. largest no. of cases are in the range of 11 to 20 dB = 54 & 25 in 1 to 10 dB in AB Gap. (Figure 2)

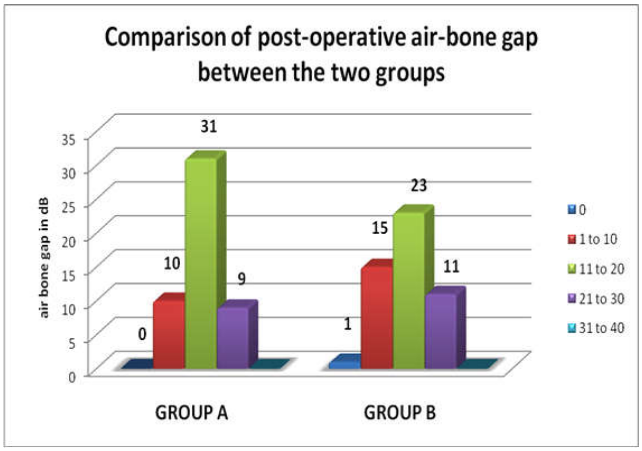

Figure 2 Comparison of Mean Post operative AB Gap between two Groups

On comparing the mean Pre operative AB gap in each group with their corresponding Post operative AB gap using paired t-test, the p value is < 0.05 which is statistically significant, which implies both the groups have significant hearing improvement following surgery. (Table 2 and Table 3) The mean improvement in hearing in our study with temporalis fascia is 14.2 dB, and with tragal perichondrium it is 14.00dB. The gain in dB in air-bone gap ranged from 5 to 30 dB. On comparing the mean Post operative AB gap of both the groups using unpaired t-test, the p value is > 0.05, which is statistically not significant. Post operative AB gain in both the groups was compared using unpaired t-test, and the p value is > 0.05, which is statistically not significant.

Table 2 Comparison of Mean Pre OP AB Gap and Post OP AB Gap in Group A

AB Gap in dB	No.	Mean	SD	Paired t test	P
Pre OP	50	31.2	6.13	t = 18.977	< 0.05
Post OP	50	17.3	5.49	df = 49	

Table 3 Comparison of Mean Pre OP AB Gap and Post OP AB Gap in Group B

AB Gap in dB	No.	Mean	SD	Paired t test		P
Pre OP	50	29.8	6.72	t = 18.521	df = 49	< 0.05
Post OP	50	16.1	6.82			

This implies that in both the groups hearing improvement is comparable. (Table 4 and Table 5)

Improvement in the air-bone gap between 0-20 dB was found in 94% of cases in the temporalis fascia group and 96 % in the tragal perichondrium group. Improvement in the air-bone gap between 21-30 dB was found in 6% cases of temporalis fascia group and 4 % in the tragal perichondrium group. This comparison of 0-20 dB and 21-30 dB improvement in air–bone gap between the two groups is statistically not significant on using Fischer exact test. (Table 6)

Table 4 Comparison of Mean Post operative Air Bone gap between two groups

Post OP AB Gap in dB	No.	Mean	SD	Unpaired t test	P
Group A	50	17.3	5.49	t = 0.968	0.335
Group B	50	16.1	6.82	df = 98	

Table 5 Comparison of Mean Post operative Air Bone gain between two groups

Post OP AB Gain in dB	No.	Mean	SD	Unpaired t test	P
Group A	50	14.2	4.986	t = 0.199	0.842
Group B	50	14.0	5.050	df = 98	

Table 6 Comparison of gain in air bone gap between the two groups

Post OP AB Gain in dB	Group A	Group B	Fisher Exact test p value
0 – 10	18 (36%)	21 (42%)	
11 – 20	29 (58%)	27 (54%)	0.795 NS
>20	3 (6%)	2 (4%)	

DISCUSSION

We have analysed our study to assess the potential of tragal perichondrium as a graft material for the reconstruction of tympanic membrane perforation. Most surgeons prefer sliced tragal cartilage or a composite graft of tragal perichondrium and cartilage as a graft material. Tragal perichondrium is easily available at the site of surgery, more resistant to infection, with comparable graft acceptance & hearing improvement. Willamson PA et al (1999) described a different approach for taking tragal perichondrium, which avoids complete removal of the tragus and only the perichondrium was dissected off from the cartilage(4). This approach is easier, and reduces cosmetic disfigurement associated with the tragal cartilage removal and replacement, and also it will help to keep both the anterior tragal perichondrium intact. In the postoperative period the shape of tragus was found to be satisfactory, and there was no disfigurement.Hartwein (1992) study shows a reduction of the air-bone gap of around 15 dB with tragal perichondrium graft (5). Jyoti P. Dabhalkar (2007)et.al., reported a 76% hearing gain was seen in temporalis fascia group which is equally good with 75% hearing gain in the tragal perichondrium group(6). Our study is comparable with SunitaChhapola, InitaMatta (2011) study, in which postoperative hearing assessed 6 months after surgery, with temporalis fascia showed an air-bone gap of less than 10dB in 82% of patients and more than 10dB in 18% patients, and air-bone gap closure with tragal perichondrium was , less than 10 dB in 78% patients and more than 10dB in 22% of patients (7). Most studies reported a mean gain in Air Bone gap in the range of 5-10 dB. John L. Dornhoffer(1997) reported a mean gain in air-bone gap in 22 patients in which tragal perichondrium was used as grafting material was 6.8 dB (8,9). Results obtained by Gupta and Mishra-92% (10) and Strahanetet.al.-82% (11), Herman-75% (12) and Singh et al.-63% (13) with temporalis fascia graft & with tragal perichondrium graft the observations of Gupta and Mishra-83%, but is higher than the result of Singh et al., -55.5%.

Summary

100 tympanoplasties were performed in 100 patients (50 using Temporalis Fascia & 50 using Tragal perichondrium). The mean improvement in Air bone gap was 14.10dB. The mean improvement in Air bone gap with Temporalis fascia was 14.2 dB. The mean improvement in Air bone gap with Tragal perichondrium was 14.00dB.

Strength of the study: A good sample size with adequate follow up

Limitation of the study: Many exclusion criteria which need surgical intervention

CONCLUSION

From the present study, we may conclude that both tragal perichondrium and temporalis fascia provide goodautograft material. Both achieve comparable and good hearing restoration. Our study will help the upcoming ENT surgeons to choose tragal perichondrium also as a graft material which provides equal success as temporalis fascia.

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