



COMPARATIVE STUDY OF TEMPORALIS FASCIA VERSUS TRAGAL PERICHONDRIUM AS A GRAFT MATERIAL IN TYMPANOPLASTY

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ABSTRACT

Background: Chronic suppurative otitis media (CSOM) is a major cause of morbidity with a large proportion of patients presenting with a tubotympanic type of disease. Tympanoplasty has been established as the standardized treatment of choice for such patients. The present study was undertaken to evaluate the temporalis fascia and tragal perichondrium as a graft material for tympanic membrane perforation, also to determine the graft take rate in different types of perforation and evaluate hearing improvement after grafting. **Method:** This prospective study included 100 patients with tub tympanic CSOM in a Tertiary Care Hospital randomized in two groups of 50 patients in each to be subjected to tympanoplasty using either temporalis fascia grafts (Group A) or tragal perichondrium grafts (Group B). History and otoscopic examination along with pure tone audiometry was performed preoperatively. Postoperative hearing improvement and graft uptake rates were compared between two groups. **Results:** The mean age of patients was 28.74 years, ranged from 15 to 45 years with male to female ratio of 1.222. Graft take rate was well in 88% of cases in both the groups. The overall mean improvement in Air bone gap (ABG) was 14.10dB. The mean gain in ABG was slightly more in group A (14.2 ± 4.98 dB) than in group B (14.00 ± 5.05 dB) but difference between two group was not statistically significant. **Conclusion:** Both the tragal perichondrium and temporalis fascia provide viable autograft material, both achieve comparable and excellent graft uptake rate as well as comparable and good hearing restoration.

KEYWORDS

Tubo-tympanic, Tympanoplasty, Temporalis fascia, Tragal perichondrium, Audiometry.

INTRODUCTION

Permanent perforation of the tympanic membrane resulting as sequelae of chronic suppurative otitis media is a major cause of deafness in developing countries due to poor nutrition, poor socioeconomic standards, lack of health education, and unhygienic habits [1]. It is a major cause for deafness in India [2]. Controversies range about every step of the operation from the incision to the material used for packing. A great deal of experimental work is being done often with contradictory results [3].

The term tympanoplasty was introduced in 1953 by Wullstein to describe the surgical technique for reconstruction of the middle ear hearing mechanism that had been impaired or destroyed by chronic middle ear disease [4]. It is defined as a "procedure to eradicate disease in the middle ear and to reconstruct the hearing mechanism, with or without tympanic membrane grafting." The first known attempt to close a perforation of tympanic membrane to improve hearing was made by Marcus Banzer in 1640 using prosthesis made of pig's bladder. Since then various graft materials like pig's bladder, Thiersch skin graft, Split-skin graft, Pedicle graft from ear canal skin, temporalis fascia graft, Vein graft, Sclera, Corneal graft, tympanic membrane homograft and perichondrium have been used for closure of the perforated tympanic membrane [5].

Although, the ideal grafting material used for tympanic membrane closure should meet certain criteria namely, low rejection rate, sufficient quantity, good tensile strength, conductive properties similar to that of tympanic membrane and easy availability [6]. The connective tissue grafts are more commonly used because of their easy availability, sturdiness and are better to handle. They act as scaffold for the epithelial healing. Tympanic membrane small perforation, moderate perforation, moderately large perforation are used to repair the tympanic membrane. However due to its anatomic proximity, translucency, and suppleness, temporalis fascia and tragal perichondrium are the two most preferred grafting materials of the contemporary otologist. There are few studies on a comparison between the two materials for the repair of tympanic membrane perforation, which has prompted this comparative study to delineate

the usefulness of each material in terms of uptake of the graft, durability of graft and their effect on hearing.

MATERIALS AND METHODS

This prospective study was carried out in the Tertiary Care Hospital at District level. Total 100 patients of aged 15 to 45 years with tubotympanic CSOM, no discharge for at least 6 weeks with intact ossicular chain and those patients willing to give written informed consent were included in the study. Patients of age <15 years and >45 years were excluded from this study as such patients (45 years and above) suffer from severe sensorineural hearing loss. Moreover, revision surgery cases, patient with diabetes, congenital hearing disorder, superimposed otomycosis, active discharge, sensorineural and mixed hearing loss were also excluded from the study.

Data collected by assigning patients of tympanic membrane perforations willing for surgery, into 2 groups by random assignment (blind randomization). One group, the control, received Temporalis fascia grafts (Group A) and other group, the cases, received tragal perichondrium grafts (Group B).

A detailed history was taken; thorough clinical examination and all relevant investigations were done. An otoscopic examination was done to record the site and size of perforation. Septic foci in the nose and throat were treated prior to ear surgery. Hearing evaluation was done by tuning fork tests (Rinne's, Weber's Absolute bone conduction), using 256, 512 and 12024 Hz tuning forks. Pure tone audiometry was then done. X-ray Mastoids (right and left) was done and the radiological features were noted. A correlation was established between the clinical features, audiogram and radiological findings. Appropriate antibiotics (Amoxicillin-Clavulanic acid, Cefixime for 2 weeks), along with antihistaminic (Cetirizine, Levocetirizine for 2 weeks), analgesics (Paracetamol for 2 weeks) and antipyretics (Paracetamol for 2 weeks) were given. Patients were subjected to examine under the microscope to confirm the diagnosis and to formulate the policy of management. Debris in the ear was clear. Examination was done under microscope and compared with otoscopic findings. Patients confirmed to have central perforations

with tubo-tympanic disease were subjected to surgical procedure. Special emphasis was laid on- Type of perforation, Presence or absence of discharge in middle ear, Ossicular integrity and pathology like granulation, polyps, etc. Surgical procedures employed included Tympanoplasty type II by the post aural approach. A separate incision was made for harvesting tragal perichondrium. Pre-operatively, Xylocaine test was done by giving with 0.1 ml of 2% Xylocaine injected intradermal on the left forearm in supine position. Informed consent of the patient and guardians was taken. Patient was kept on empty stomach overnight. Preoperative doses of suitable i.v antibiotic were given. One group underwent tympanoplasty using temporalis fascia and the other group underwent the same operation using tragal perichondrium. All patients were operated under local anesthesia and were achieved by using 2% Xylocaine in subcutaneous tissue of post auricular region and external auditory canal using 26 number needle and syringe. Cotton balls soaked in a solution of 4% Xylocaine with adrenaline were used for local anesthesia of the tympanic membrane and Gel foam was used to stop bleeding during the procedure. Tympanic membrane graft was placed by underlay technique. Ossicular continuity checked intra-operatively, no middle ear spaces were used and the ear canal was packed using Gel foam.

Post-Operatively, patients were put on appropriate antibiotics and were given for one week along with analgesics, antihistaminic and multivitamins. In cases of suspected postoperative infections, antibiotics and antihistaminic was continued up to 2 weeks. Weber's test was done. Mastoid dressing for temporalis fascia cases and ear dressing for tragal perichondrium cases was done on the 3rd post-operative day. Gel foam placed in the ear canal surgery was not disturbed. Post-Operatively graft failure occurs due to post-operative infection, post-operative pharyngitis along with cough and sneeze, intra-operative handling of graft, intra-operative improper placement of graft. Topical antibiotic drugs were prescribed, to be put after 2 weeks postoperatively. Patients receiving the tragal perichondrial grafts were discharged the same day and patients operated by post aural route were discharged on the 2nd postoperative day. All was asked to follow up weekly. The condition of the graft was appreciable from the 2nd week onwards. All patients were examined by otoscope and under the microscope at 4 weeks to determine the condition of the graft. Follow up was then done at monthly intervals. Pure tone audiometry was done at 4 weeks postoperatively, after the graft was fully taken and repeated after 3 and 6 months. At follow up, the graft was inspected for medialization and development of granulations. The ear canal was inspected for development of granulation in the region of posterior canal skin incision. Granulations if present were cauterized by applying Tricyclic acid over them. Post aural and end aural wounds was periodically inspected for any infection or collection and if any found, appropriate antibiotics and anti-inflammatory drugs was given.

OBSERVATIONS AND RESULTS

Total 100 myringoplasties were performed in 100 patients, of them 50 were operated using temporalis fascia and another 50 were operated using tragal perichondrium. The mean age of patients was 28.74 years, ranged from 15 to 45 years with male to female ratio of 1.222. Graft take rate was well in 88% of cases in both the groups as shown in table 1.

Table 1: Comparison of various parameters between two groups

Parameters	Group A	Group B	P value
Mean age	28.26±7.51	29.22±6.20	0.488
Sex	Male	28(56%)	0.8407
	Female	22(44%)	
Type of Central Perforation	Large	12 (24%)	0.834
	Moderate	31 (62%)	
	Small	7 (14%)	
Site of Involvements	Bilateral	15 (30%)	0.656
	Unilateral	35 (20%)	
Type of Anaesthesia	GA	22 (44%)	0.161
	LA	28 (56%)	
Route of Surgery	Endomeatal	4 (81%)	0.338
	Postaural	7 (14%)	
Graft take up	Yes	44 (88%)	>0.05
	No	6 (12%)	

In both the groups, maximum numbers of cases were in the range of 21-30 db ABG (52 patients) followed by range of 31-40 db and few patients in 1-10db ABG group as shown in figure 1. There was not

statistically significant difference between pre-operative ABG of two group, (p= 0.5441).

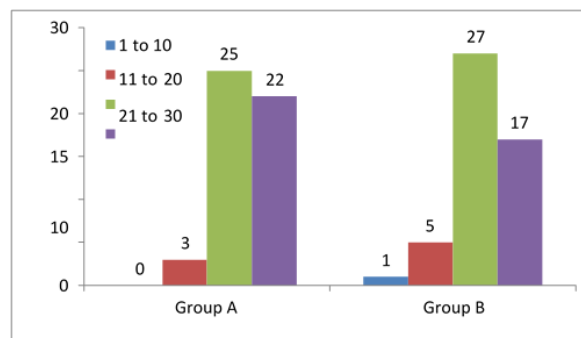


Figure 1: Comparison of Pre-op air-bone gap between the two groups

Figure 2 shows the distribution of Post-op air-bone gap between the two groups. Most of the cases were in the range of 11 to 20 dB, 54 cases and 25 in 1 to 10 dB in ABG Gap.

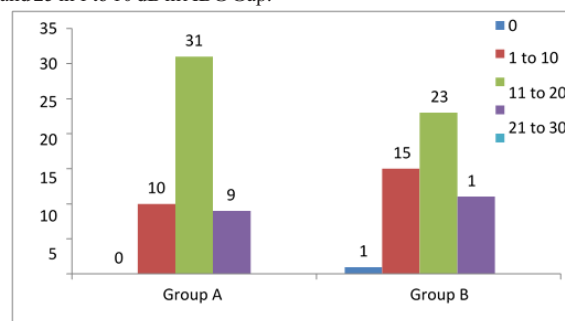


Figure 2: Comparison of post-operative air-bone gap between the two groups

Table 2 show the comparison of gain in air bone gap between the two groups. The overall mean improvement in Air bone gap was 14.10dB. The mean gain in air-bone gap was slightly more in group A (14.2 ± 4.98 dB) than in group B (14.00 ± 5.05dB) but difference between two group was not statistically significant, (P value-0.383).

Table 2: Comparison of gain in air bone gap between the two groups

Gain ABG dB	Group A	Group B	P value
0 - 10	18 (36%)	21 (42%)	0.795 NS
11 - 20	29 (58%)	27 (54%)	
>20	3 (6%)	2 (4%)	

DISCUSSION

Tympanoplasty is a term used to describe reconstruction of the tympanic membrane and sound conducting mechanism of the ear. Since its first description in 1952 by Wullstein and Zollner various materials have been used for tympanoplasty [7, 8]. The standard graft material which is widely used is temporalis fascia. Most surgeons prefer sliced tragal cartilage and even composite graft of tragal perichondrium and sliced cartilage as a graft material for reconstruction. Tragal perichondrium is easily available at the site of surgery, more resistant to infection, with comparable graft acceptance and hearing improvement. The present study was designed to evaluate the usefulness of tragal perichondrium as a graft material for reconstruction of tympanic membrane perforation. Total 100 myringoplasties were performed in 100 patients of age between 15 to 45 years and only when their ear was dry for at least 6 weeks which is comparable with the study done by Dabholkar et al [9] and Shetty et al [10]. Patients were selected from our outpatient department, who came from low socioeconomic status, presented with decreased hearing or ear discharge not responding to medication. We have compared the results of tragal perichondrium and temporalis fascia grafts used for the repair of perforated tympanic membrane using underlay technique. Both tragal perichondrium and temporalis fascia are accessible near the operative site, available in adequate amount, have excellent contour, can be thinned down and possess excellent survival capacity. Both being mesodermal in origin, they are free from the possibility of

post-operative cholesteatoma formation. Essentially all the myringoplasties were done in dry central perforation with underlay technique for both temporalis fascia and tragal perichondrium so that uniformity of study can be obtained. For the same reason patients with central septic foci were not operated until the septic foci were removed. To maintain uniformity of comparison cases with very narrow ear canals were excluded and difficult anterosuperior perforations were also excluded. By and large most of the patients were operated by postaural route under general anaesthesia. Few technically favourable cases were operated by endomeatal approach taking care that this approach will not compromise the placement of graft.

Temporalis fascia is being used for ages for grafting tympanic membrane perforation. It is supposed to be a stable, tough and easy to maneuver piece of graft and these qualities are accepted by all. Fascia and perichondrium display acoustic properties similar to those of tympanic membrane. Tragal perichondrium is stable with excellent survival capacity as it has inherent properties of bradytrophia, absence of contraction and swelling. In revision cases when obtaining Temporalis graft in adequate amount was not possible Tragal Perichondrium was used as it was available in abundance.

The overall graft take up rate was found to be 88% at 6 months duration. For Tragal Perichondrium graft the take up rate was 88% and that for Temporalis fascia also the take up rate was 88%, which was statistically not significant. These results are consistent with those of Dabholkar et al [9]; in their study temporalis fascia achieved a graft uptake of 84% and tragal perichondrium achieved a success rate of 80% but found no statistically significant difference between them. Also, Shetty et al [10] showed graft uptake in the temporalis fascia group was 92% and in the tragal perichondrium group was 96%. Sood et al [11] reported the overall rate of graft uptake was 72.5%. At 2 months, there was 95% graft uptake with Tragal cartilage with perichondrium and 90% with Temporalis fascia, this difference was not statistically significant. A study by Kalcioğlu et al showed a graft survival rate of 86.1% in the fascia group and 95% in the cartilage group among 307 patients [12]. The lower results in our study may be attributed to the smaller sample size.

Most graft failures seen in follow up periods were due to infection probably transmitted either along the Eustachian Tube or along the External Auditory Canal. The patients' population attending our hospital was mostly from low socioeconomic status. Many had poor personal hygiene and poor nutritional status which contributed to higher rate of graft rejection. 96% of our cases showed improvement in hearing while 4% of them show no improvement at the end of 6-month follow up. About 100% of the patients operated with temporalis fascia showed hearing improvement while 96% of cases who were operated with tragal perichondrium show improvement in hearing. The mean improvement in hearing with temporalis fascia was 14.2 dB and with tragal perichondrium it was 14.00 dB. The gain in dB in air-bone gap ranged from 5 dB to 30 dB. Improvement in air-bone gap between 0-20 dB was found in 96% of cases in both temporalis fascia and tragal perichondrium. Improvement in air bone gap between 21-30 dB was found in 4% cases of both temporalis fascia and tragal perichondrium. This comparison of 0-20 dB and 21-30 dB improvement in air-bone gap between the two groups was statistically not significant. These findings are correlated well with the study done by Dabholkar et al [9] and Sood et al [11]. The current study also compares well with Sengupta and Basak study [13], whose postoperative hearing assessed after 6 months of surgery, with temporalis fascia graft showed air bone gap of less than 10 dB in 82% of patients and more than 10 dB in 18% patients, air bone gap closure with tragal perichondrium was less than 10 dB in 78% patients and more than 10 dB in 22% of patients.

CONCLUSION

From the observations of present study, we may conclude that both tragal perichondrium and temporalis fascia provide viable autograft material. Both achieve comparable and excellent graft uptake rate as well as comparable and good hearing restoration. Both materials are mesodermal in origin which does not exclude the risk of iatrogenic Cholesteatoma.

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