Temporalis fascia versus areolar temporalis fascia in type 1 tympanoplasty: A randomized comparative study

Dr. Yarlagadda Lakshmi Sravya
Resident, Department of ENT, KIMS, Karad

Dr. A. D. Havle
Prof & Hod, Department of ENT, KIMS, Karad

Dr. Kaenat Ahmed
Resident, Department of ENT, KIMS, Karad

Abstract---To study outcome of various autologous grafts used in cases of type-1 tympanoplasty. To compare between temporalis fascia and areolar temporalis fascia (Fool's fascia) used as a graft materials in type-1 tympanoplasty. Tympanoplasty is the commonest surgery of the middle ear carried out to improve hearing in patients with conductive hearing loss. Wullstein first coined the term tympanoplasty in 1953(1). Myringoplasty or type 1 tympanoplasty is an operation for reconstruction of a tympanic membrane perforation. Type I tympanoplasty refers to restoration normal anatomy of middle ear. Although the different graft materials are being used for closure of tympanic membrane perforation the most ideal material is unknown yet. Of the autologous materials, temporals fascia is the most frequently used for all perforations due to its easy availability, the abundance of tissue. Various other autologous materials have been used. They are either locally accessible such as periosteum, perichondrium either alone or with attached cartilage, subcutaneous tissue, skin from the external auditory canal (EAC) or elsewhere and also the fat. The fat is harvested usually from ear lobule or post auricular region though it can be from any other site. Fascia lata and vein are distantly located autograft. All these materials varied due ease of harvesting, preparation time, ease of its placement, viability, graft uptake and desired improvement in hearing.(2) Several literatures are available regarding the study of different graft materials. Using temporalis fascia in type 1 tympanoplasty the graft take-up was 87.5% in study by Gibb and Chang et al(3). The successful healing of tympanic membrane defect using areolar temporalis fascia in type 1 tympanoplasty was found in 98.54% of the
cases in study by Cueva et al. 1999. The study was conducted during the period November 2019 to April 2021 at the department of ENT, KIMSDU, Karad. A total of 58 patients were included in this study. All enrolled cases were put into two groups (Group A and Group B) on first come first basis before subjecting to type-1 tympanoplasty. Temporalis fascia and areolar temporalis fascia (fool’s fascia) were used as a graft materials in Group A and Group B cases respectively during type-1 tympanoplasty. PTA was done by the 6th month to assess the hearing. During follow up all cases were assessed based on the color of graft, nature of ear discharge, position and placement of graft, residual defect, if any and hearing. Hearing gain of 13.69±5.87 dB in temporalis fascia group and 12.69±4.05dB in areolar temporalis fascia group was noted. Graft uptake was seen in 89.7% and 86.2% in Group A, B respectively at the end of 6th month. There was no significant difference in overall outcome in both the groups. The temporalis fascia and areolar temporalis fascia were equally effective graft materials in type 1 tympanoplasty.

**Keywords**—areolar temporalis fascia, temporalis fascia, tympanoplasty.

**Introduction**

Chronic inflammation of the middle ear cleft i.e, Eustachian tube, middle ear, aditus and mastoid air cells with at least 2-4 weeks of recurrent discharge through a tympanic membrane perforation is defined as chronic suppurative otitis media. In developing countries like India, CSOM is highly prevalent. About 65–330 million people worldwide are affected by CSOM as per The World Health Organization (WHO) and approximately 28000 deaths per annum are due to csom complications. The incidence of CSOM is recorded by Monasta et al to be 31 million cases globally. CSOM leads to permanent pathological changes in the tympanic membrane including atelectasis, perforation, ossicular destruction, cholesteatoma, retraction pocket development, tympanosclerosis, polyp, and formation of granulation tissue. It causes significant conductive hearing loss. Reconstruction of conductive hearing mechanism as well as eradication of disease process is the targeted goal in treating chronic suppurative otitis media.

Tympanoplasty is the middle ear surgical procedure carried out to improve hearing in patients with conductive hearing loss. Myringoplasty can be defined as the surgical repair of the tympanic membrane. Wullstein in 1956 classified tympanoplasty, with myringoplasty being classified as a Type I tympanoplasty. The closure of perforation is achieved using various graft materials. The available graft materials are classified as autologous, allogenous and heterogeneous. As yet there is no ideal graft material available. The graft materials vary regarding their site of harvesting, time to prepare the graft, viability, graft uptake, ease of placement and improvement in hearing. Several literatures are available using different graft materials.
Of the autologous materials, temporalis fascia is the most frequently and popularly utilized for all perforations given its availability, the abundance of tissue and ease of harvesting and use.\(^{(15)}\) Perichondrium, Cartilage from either the tragus or concha provides an alternative material due to its long-term reliability.\(^{(16)}\) Easily harvested via a postauricular or endaural approach, a separate scalp incision, hidden in the hairline, may also be used during a permeatal approach. Other autologous materials have been used, either locally accessible such as periosteum, other skin graft and fat, the latter usually being harvested from the lobule or post auricular region though abdominal fat has also been used. Fascia lata and vein provide a more distant autograft.\(^{(17,18,19)}\) Experimental investigations of allogeneic materials include:

- extracellular matrix in the form of urinary bladder,\(^{(20)}\)
- stem cells\(^{(21)}\)
- Alloderm, processed from human allograft skin and rendered immunologically inert,\(^{(22)}\)

Several xenogenous materials have been investigated:

- Equine and bovine pericardium were found to be inferior to temporalis fascia.\(^{(23)}\)
- Basic fibroblast growth factor (FGF)

In a study conducted by Gibb and Chang et al. in 365 patients who underwent Type 1 tympanoplasty using temporalis fascia showed a take-up of 87.5\%\(^{(3)}\). In a study conducted by Cueva RA. Am J Otol. 1999, 98.54\% of the cases which underwent tympanoplasty using areolar temporalis fascia as graft material showed successful graft uptake.\(^{(4)}\)

**Temporalis fascia**

Temporalis fascia was first used in myringoplasty by Ortegren in 1958-59, Heermann (1961) and Storrs (1961). Temporalis fascia the most frequently used graft material for closure of the tympanic membrane perforation.

**Advantages of temporalis fascia**

Location of donor site.
Easy to harvest.
Close biological and segmental kinship
Low Body metabolic rate which, requires less nutrition, high survival.
No size limitation.
It can be used as overlay and underlay grafting.

**Materials and Methods**

The study was conducted during the period November 2019 to April 2021 at the department of ENT tertiary care teaching hospital.
Inclusion criteria

All patients requiring reconstructive surgical treatment (type 1 tympanoplasty) for small and medium sized perforation of tympanic membrane.

Exclusion criteria

- Patients with large, subtotal or total perforation
- Patients with previous history of ear surgery in the same ear.
- Patients having sensorineural hearing loss.
- Patients with congenital ear deformities.
- Patients with ossicular dysfunction.

All the patients of tympanic membrane perforation fulfilling the indications of type 1 tympanoplasty were included in the study. After obtaining clearance and approval from the institutional ethics committee all patients with small and medium sized perforation fulfilling the indications for surgical treatment (tympanoplasty type-1) were enrolled in the study. Prior informed consent was obtained from every patient. All patients were evaluated by means of proper history, otomicroscopic and otoendoscopic examination and pure tone audiometry and randomly grouped into two on first come first basis before subjecting to type-1 tympanoplasty. During type-1 tympanoplasty in cases of group A and group B, temporalis fascia and areolar temporalis fascia (fool’s fascia) were used as a graft material respectively. In all cases postaural sutures were removed on the 7th post-operative day before discharge. All patients were followed-up for period of 6 months after discharge. During follow up at 3rd and 6th month, all cases were assessed based on the color of graft, nature of ear discharge, position and placement of graft, residual defect, if any and hearing acuity. The good graft take-up, non-doctor dependent dry ear and improved hearing were considered as indicators of successful treatment.

Statistical analysis

SPSS 16.0 version was used to analyse the data. Unpaired sample t-test was used to compare between improvements in hearing in both the groups. Chi square test for association was done to compare between genders of patients, side, site of perforation and pneumatization of mastoid from both groups. Probability value <0.05 was considered as significant.

Observation and Results

A total of 29 patients were included in each group. In group-A 41%, and 59% cases were males female respectively. And similarly in group-B, 31% and 69% were males and females. The overall number of female patient were higher than male (M: F ratio= 1:1.76) amongst either groups. The mean age amongst all patients was 32.24 ± 10.82 and 32.24 ± 10.38 years in group A and group B respectively. There was no significant difference in the demographic data amongst both the groups.
48.2% cases of Group-A were found to have left sided perforation, 38% right and 13.7% had bilateral perforation who underwent type-I tympanoplasty in one ear only during study period. In Group-B, 45% had left, 31% right and 24% bilateral perforation. There was no significant difference between sides of perforation in both the groups. In Group A, medium and small sized perforation was noted in 18 and 11 cases respectively, whereas in Group B, it was noted in 15 and 14 cases. No significant difference between sizes of perforation in both the groups.

In this study it was observed that 2(6.9%) patients had anteroinferior perforation, 8(27.6%) patients had anterior perforation, 1(3.2%) patients had anterosuperior perforation, 5(17.2%) patients had central perforation, 9(31%) patients had posteroinferior perforation and 1(3.2%) patient had posterosuperior perforation in group-A. In group-B we observed that 2(6.9%) patients had anteroinferior perforation, 8(27.6%) patients had anterior perforation, 7(24.1%) patients had central perforation, 7(24.1%) patients had posterior perforation and 3(10.3%) patient had posteroinferior perforation, 2(6.9%) patients had posterosuperior perforation and no patients had anterosuperior perforation. There was no significant difference between site of perforation in both the groups.

Mastoid pneumatisation was found to be diploiec in 6.9%, pneumatic in 6.9% and sclerotic in 86.2% patients of group-A.in group-B, it was be diploiec in 3.4%, pneumatic in 10.3% and sclerotic in 86.2% patients. There was no significant difference in mastoid pneumatization between both the groups. Graft uptake was noted in 89.7% and 86.2% in Group A, B respectively at the end of 6th month which showed no significant difference. Medialization of graft was noted in 6.9% in Group A and B at the end of 6th month which showed no significant difference. Residual perforation was observed in 3.4%, 6.9% in group A, B respectively at the end of 6th month which showed no significant difference.

There was marginal difference of hearing loss in either groups before surgical intervention which was 38.72± 12.81 dB in group-A and 38.41± 12.26 dB in group-B. Also, after the surgical intervention the difference in hearing loss was marginal i.e. 25.03±6.94 dB and 25.72±8.21 dB in group-A group-B respectively. Hearing gain noted in either groups was 13.69±5.87 and 12.69±4.05 dB in group-A and group-B respectively. Graft uptake was 89.7% and 86.2% in Group A, B respectively at the end of 6th month follow-up. Overall outcome in improvement of hearing as well as status of the graft uptake did not show any significant difference in either groups.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Group A (Temporalis fascia)</th>
<th>Group B (Areolar temporalis fascia)</th>
<th>Chi square statistic</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Graft uptake</td>
<td>26</td>
<td>25</td>
<td>0.35</td>
<td>0.84</td>
</tr>
<tr>
<td>Medialization of</td>
<td>2</td>
<td>2</td>
<td>6.9</td>
<td></td>
</tr>
</tbody>
</table>
Table 2
Improvement in hearing in both groups

<table>
<thead>
<tr>
<th>Hearing (in Decibles)</th>
<th>Group A</th>
<th>Group B</th>
<th>t-statistic</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean</td>
<td>SD</td>
<td>N</td>
</tr>
<tr>
<td>Pre-op</td>
<td>29</td>
<td>38.72</td>
<td>12.81</td>
<td>29</td>
</tr>
<tr>
<td>Post-op</td>
<td>29</td>
<td>25.03</td>
<td>6.94</td>
<td>29</td>
</tr>
</tbody>
</table>

**Discussion**

Tympanoplasty is a procedure to repair the tympanic membrane perforations and simultaneously ensuring ossicular continuity using various techniques and graft materials. In this study of 58 cases, females outnumbered males. The male to female ratio is 1:1.76. The mean age amongst both groups was 32 ± 11 years. In cases with bilateral perforation underwent surgery only in one ear during the study period. In group-A, 48.2% and 38 % of cases had perforation in left and right ear respectively, whereas 13.7% it was bilateral perforation. In group-B, 45% and 31 % of cases had perforation in left and right ear respectively, whereas 24% it was bilateral perforation. There was no significant difference between side of perforation in both the groups.

Size of tympanic membrane perforation was found to be small and medium in 11 and 18 cases of group-A, whereas in group-B, it was 14 and 15 cases respectively. However, it was not significant statistically. In a similar study by Wasson et al. [24] size of the perforation was also not statistically significant. Graft uptake was seen in 89.7% and 86.2% in Group A, B respectively at the end of 6th month which showed no significant difference. Medialization of graft was noted in 6.9% in Group A and B at the end of 6th month which showed no significant difference. Residual perforation was observed in 3.4%, 6.9% in Group A, B respectively at the end of 6th month which showed no significant difference. In a similar study by Vartiainen et al [25], in 24 out of the 38 myringoplasty cases failure of graft uptake is 63%.

Preoperative hearing loss of 38.72± 12.81 dB was noted in group-A and 38.41± 12.26 dB in group-B. Postoperatively it was 25.03± 6.94 dB in group-A and 25.72± 8.21 dB in group-B. The status of hearing loss was almost similar in either groups preoperatively and improved after surgical intervention. Hearing gain of 13.69± 5.87 and 12.69± 4.05 dB in group-A and B was found. In a study by Bhardwaj et al. [26] the air-bone gap closure was found to be 11.41± 8.288 dB in temporalis fascia group and 14.98± 9.915 dB in conchal cartilage group at the
end of 6 months. Good graft uptake was seen in 89.7% in temporalis fascia group and 86.2% in areolar temporalis fascia group at the end of 6th month which showed no significant difference in outcome. In study by Neeraj et al. (27), the rate of graft uptake using cartilage and temporalis fascia is 90% and 80% respectively. A study by Kadir et al. (28), the graft uptake rate is 92.6% and 90% using tragal perichondrium and temporalis fascia respectively. The graft uptake rate of 98.5% using areolar temporalis fascia is seen in study by RA Cueva et al. (29).

Conclusion

Hearing improvement of 13.69±5.87 dB in group-A and 12.69±4.05 dB in group-B was noted however, it was not significant. Overall success rate was marginally more in group A- temporalis fascia (89.7%) than group B- areolar temporalis fascia (86.2%).

References