EFFICACY AS A GRAFT: TEMPORALIS FASCIA VS TRAGAL CARTILAGE PERICHONDRIUM, A RETROSPECTIVE COMPARATIVE STUDY

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ABSTRACT

Background: Chronic otitis media(COM) is an inflammatory process of the middle ear space that results in long term or more often, permanent changes in the tympanic membrane (TM) which includes atelectasis, dimer formation, perforation, tympanosclerosis, retraction pocket formation or cholesteatoma formation. With the advent of antibiotics, modern anaesthetic techniques and modern instruments, the aim is to produce a dry ear and it has changed the outcomes of the surgery drastically. Aim: To conduct a retrospective comparative analysis to evaluate the long-term postoperative results of tragal perichondrium and temporalis fascia grafts by analyzing the anatomic-auditory outcomes.

Methods and Material: A retrospective study was performed in the Department of Otorhinolaryngology on patients diagnosed with COM and underlay type 1 tympanoplasty was done from September 19, 2022 to September 19, 2023. A detailed history and clinical examination of the patients of chronic otitis media was done and case selection was done randomly after satisfaction of inclusion and exclusion criteria. The cases were subjected to microscopic examination and pre-operative audiological test (pure tone audiometry) was performed in each case. Underlay Type 1 tympanoplasty was done using tragal perichondrium and temporalis fascia graft and postoperative follow up was done Results: Majority of the selected patients showed mild to moderate hearing loss preoperatively. At 3 months postoperative 90% and 85% operated with temporalis fascia and tragal cartilage perichondrium respectively as a graft showed improvement in hearing. Graft uptake was seen in 85% and 80% of patients who underwent surgery with tragal cartilage perichondrium and temporalis fascia graft respectively at the end of 3 months. Graft failure was seen in 15% and 20% of cases who underwent surgery with tragal cartilage perichondrium and temporalis fascia respectively at the end of 3 months. Conclusion: Temporalis fascia and Tragal cartilage perichondrium both are excellent graft material to repair the tympanic membrane. Graft uptake rate and hearing improvement were comparable in both grafts but hearing improvement was slightly better in case of temporalis fascia graft and graft uptake rate was slightly better in case of Tragal cartilage perichondrium graft.

INTRODUCTION

Chronic otitis media(COM) is an inflammatory process of the middle ear space that results in long term or more often, permanent changes in the tympanic membrane(TM). Higher incidence of COM has been observed in developing countries. In India, the overall prevalence is 46 and 16 persons per thousand in rural and urban population respectively.(1)

Clinically COM is divided into tubotympanic or safe type or mucosal variety and atticoo-antral or unsafe type or squamosal variety. Tubotympanic type is generally characterized by intermittent, odourless, profuse mucoid ear
discharge, mild to moderate conductive hearing loss with comparatively less risk of serious complications than squamous variety. Control of infection and repair of perforated tympanic membrane are the mainstay of treatment. Commonly in attico-antral type, there is involvement of posterosuperior part of the middle ear cleft, bone eroding process like cholesteatoma formation, granulations or osteitis resulting in high risk of complications. It is usually characterized by scanty, foul smelling, purulent ear discharge. (2)

With the advent of antibiotics, modern anesthetic techniques and modern instruments, the aim is to produce a dry ear and it has changed the outcomes of the surgery drastically (3). Tympanoplasty includes repairing of tympanic membrane after having a look into the middle ear (4). The first known attempt to close a perforation of TM, to improve hearing was made by Marcus benzer in 1640. The fundamental principles of surgical procedure was first described by Wullstein (4). Size and location of perforation, tympanosclerosis, allergies, eustachian tube dysfunction and active infection in ear must be considered to evaluate surgical outcome (5).

Various autografts have been used for repairing of the tympanic membrane perforation like full thickness skin graft, pedicled skin grafts (Frenckner 1955), split skin graft (Wullestein 1952 and Zollner 1953), fascia grafts (Heermann 1960), perichondrium (Jansen 1963 and Goodhill 1967) and vein graft (Shea 1960). Each one of these graft materials has its own advantages and disadvantages over each other. Graft materials like temporalis fascia, tragal perichondrium are the most commonly used graft material in myringoplasty. Taking the above mentioned facts into consideration, this study was taken up to compare the two graft materials i.e. temporalis fascia and the tragal perichondrium. The study includes the advantages and disadvantages of these graft materials in comparison to each other.

As proved by literature ideal graft is the one that is easy to harvest with less invasive procedure, with shorter duration of hospitalization, less morbidity to donor site, lesser risk of infections, with no transfer of infectious disease as can be with allografts and costs less as comparatively (8). Temporalis fascia is the most common graft material to be used because of it’s abundance and ease to harvest, can be taken via same post auricular incision and can also be used in revision surgery (5,9,10). Perichondrium can be used alone or with cartilage and can be harvested from the tragus [9]. This graft is easy to harvest, no preparation of surgical site (shaving) is required, size is usually appropriate and incision carries comparatively lesser morbidity [9].

**AIM**
To conduct a retrospective comparative analysis to evaluate the long-term postoperative results of tragal perichondrium and temporalis fascia grafts by analyzing the anatomic-auditory outcomes.

**OBJECTIVES**
1. To do a retrospective comparative study of Underlay type 1 Tympanoplasty with temporalis fascia and Tragal Perichondrium as graft material.
2. We did this study to know the results of the surgery with respect to:
   - graft uptake
   - hearing improvement

**MATERIALS AND METHODS**
A retrospective observational study was performed in the Department of Otorhinolaryngology on the patients diagnosed with COM and underwent Underlay type 1 Tympanoplasty fulfilling the inclusion criteria from September 19, 2022 to September 19, 2023. A detailed history and clinical examination of the patients of chronic otitis media was done according to the proforma and case selection was done randomly. The cases were subjected to microscopic examination and pre-operative audiological test (pure tone audiometry) was performed in each case. Routine blood tests including bleeding time and clotting time, sugar estimation, renal function test, viral serology for HIV, HBV, HCV were done. X-rays and CT scans for mastoid and paranasal sinuses were done whenever required.
INCLUSION CRITERIA
Inactive mucosal COM
The ear should be dry minimum for 6 weeks with intact ossicular chain.
persistent traumatic perforation.
Patients between age group 15 – 45 years of any gender

EXCLUSION CRITERIA
Unsafe COM.
Safe COM with sensorineural hearing loss.
Patients < 15 years and > 45 years.
Wet ear.
All AOM cases.
Congenital hearing disorder.
Previous history of ear surgery.
ossicular chain pathology.

OPERATIVE PROCEDURE
A total of 40 patients were selected for the study considering the inclusion and exclusion criteria. Patients were randomized and subjected to underlay type 1 tympanoplasty by using tragal perichondrium or temporalis fascia.

Positioning and preparation:
Patient was positioned in reversed Trendelenburg position with a head ring. Antiseptic draping was done with 10% betadine solution.

Anesthesia:
Cases were operated under general or local anesthesia after Xylocaine sensitivity test. General anesthesia was used in apprehensive patients. Local anesthesia was achieved by using 2% xylocaine with 1:200,000 adrenaline in the subcutaneous tissue of post auricular region and four quadrant of external auditory canal.

Follow Up:
Patients were followed up after 1st week, 2nd week, one month and three months after surgery. At follow up patients were evaluated by otoscopic examination to determine the condition of the graft, pure tone audiometry was done and the air bone gaps were assessed.

Data Analysis
Data(observations) were tabulated on a spread sheet by using Microsoft excel and then Statistical analysis of the patients was carried out with student’s t-test and “z” test. A p value<0.05 was considered statistically significance.

RESULTS

Table 1: Age wise distribution

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>15-20 YRS</td>
<td>12</td>
</tr>
<tr>
<td>21-30 YRS</td>
<td>14</td>
</tr>
<tr>
<td>31-40 YRS</td>
<td>10</td>
</tr>
<tr>
<td>40-45 YRS</td>
<td>4</td>
</tr>
</tbody>
</table>
Table 2: Sex wise distribution

Table 3: Pre-operative hearing levels

<table>
<thead>
<tr>
<th>Preoperative a-b gap</th>
<th>Number of patients and the planned graft material</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Temporals fascia</td>
<td>Tragal perichondrium</td>
</tr>
<tr>
<td>&lt;20 dbhl</td>
<td>12</td>
<td>11</td>
</tr>
<tr>
<td>21-40dbhl</td>
<td>8</td>
<td>9</td>
</tr>
</tbody>
</table>

Majority of the patients showed mild to moderate hearing loss
57.5% had a-b gap <20 dbhl
42.5% had a-b gap 21-40 dbhl
None of the patients had a-b gap >40dbhl

Table 4: Post operative hearing levels at the end of 3 months

<table>
<thead>
<tr>
<th>Post operative a-b gap</th>
<th>Number of patients and the planned graft material</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Temporals fascia</td>
<td>Tragal perichondrium</td>
</tr>
<tr>
<td>&lt;20 dbhl</td>
<td>16</td>
<td>14</td>
</tr>
<tr>
<td>21-40dbhl</td>
<td>6</td>
<td>4</td>
</tr>
</tbody>
</table>

In post operative hearing analysis
75% of patients showed a-b gap <20db
25% patients showed a-b gap 21-40db
None of the patients had ab gap >40db

Table 5: Post-operative hearing improvement levels

<table>
<thead>
<tr>
<th>Mean change in hearing levels in db</th>
<th>Number of patients and graft materials</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Temporals fascia</td>
<td>Tragal perichondrium</td>
</tr>
<tr>
<td>No change or worsen</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>1-15db</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>16-30db</td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>&gt;30db</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Hearing after 3 months showed improvement in 35 out of 40 patients. Amongst them 18 out of 20 i.e., 90% operated with temporalis fascia as a graft material showed improvement in hearing and 17 out of 20 i.e. 85% operated with tragal perichondrium as graft showed improvement in hearing. There is no statistically significant difference in hearing improvement levels amongst both the graft materials for tympanoplasty (z=0.36, p>0.05).

Table 6: Mean hearing levels in tympanoplasty using Tragal perichondrium and Temporalis fascia

<table>
<thead>
<tr>
<th>Name of graft</th>
<th>Mean levels of hearing loss</th>
<th>Post operative change in hearing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Preoperative hearing loss</td>
<td>Post operative hearing loss</td>
</tr>
<tr>
<td></td>
<td>levels (db)</td>
<td>levels (db)</td>
</tr>
<tr>
<td>Temporalis fascia</td>
<td>380/20(19)</td>
<td>189/20(9.45)</td>
</tr>
<tr>
<td>Tragal perichondrium</td>
<td>450/20(22.5)</td>
<td>270/20(13.5)</td>
</tr>
<tr>
<td>Total</td>
<td>830/40</td>
<td>459/40</td>
</tr>
</tbody>
</table>

Mean improvement level in hearing with temporalis fascia- 10.55db
Mean improvement levels in hearing with tragal perichondrium- 9db
P>0.05, we found that there was no statistically significant difference in mean improvement in hearing amongst temporalis fascia or tragal perichondrium grafts.

Table 7: Graft uptake rate

<table>
<thead>
<tr>
<th>Type of graft</th>
<th>Graft uptake</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tragal perichondrium</td>
<td>17/20</td>
<td>85%</td>
</tr>
<tr>
<td>Temporalis fascia</td>
<td>16/20</td>
<td>80%</td>
</tr>
<tr>
<td>Total</td>
<td>33/40</td>
<td>82.5%</td>
</tr>
</tbody>
</table>

The above table indicated that graft uptake was seen in 85% of patients i.e., 17 out of 20 who underwent surgery with Tragal perichondrium as graft and 80% graft uptake (i.e., 16/20) was noted where temporalis fascia was taken as a graft after 3 months. However there was no statistical significant difference found with respect to graft uptake with respect to type of graft. (z=0.36, p>0.05).

Table 8: Graft failure rates

<table>
<thead>
<tr>
<th>TYPES OF GRAFT</th>
<th>FAILURE RATES</th>
<th>PERCENTAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEMPORALIS FASCIA</td>
<td>3/20</td>
<td>15%</td>
</tr>
<tr>
<td>TRAGAL PERICHONDRIUM</td>
<td>4/20</td>
<td>20%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>7/40</td>
<td>17.5%</td>
</tr>
</tbody>
</table>

The above table indicated that graft failure was seen in 15% of cases i.e., 3/20 who underwent surgery with tragal perichondrium as graft and 20% graft failure i.e. 4/20 was noted where temporalis fascia was used as a graft material at the end of 3 months. There was no statistical significant difference found with respect to graft failure among both the types of graft material(z=0.36,p>0.05).

DISCUSSION
This is the retrospective study of 40 tympanoplasties on patients between the age of 15 to 45 years, who were admitted in the Department of ENT and Head and Neck surgery at Assam medical college and hospital, Dibrugarh between sept 2022 to sept 2023.
20 patients were subjected to tympanoplasty with temporalis fascia and 20 with tragal perichondrium. Post operatively patients were followed up for 3 months duration.
Anatomical and functional outcomes are influenced by multiple variables, such as the location and size of the perforation, duration of perforation and status of the ear(11–14). General nutritional status and socioeconomic conditions may also influence the outcome.
Temporalis fascia and tragal cartilage perichondrium are the most frequently used materials for Underlay type 1 Tympanoplasty in literature because of the ease of graft harvesting and high surgical success rate. However the superiority amongst them has to be yet determined.

**Graft uptake rate**

The graft uptake rate after 3 months was 82.5%. In our study, graft uptake rate for temporalis fascia was 80% as compared to tragal perichondrium was 85%.

Graft uptake rate was slightly better for tragal perichondrium (not significant p>>0.005). This marginal difference however, is not significant. These reports compare well with similar study conducted by Jyoti P Dabholkar (2007) whose postoperative graft uptake rate with temporalis fascia was 84% and tragal perichondrium showed 80%. Jain CM (1968) who reported 83.33% success rate with temporalis fascia, Ahadsaet al.(1986), with 83.30% success with homologous temporalis fascia and Blanshardjd et al. (1990), 78% uptake-rate with temporalis fascia in pediatric tympanoplasty. Pkparida, S.knochikattil et al.(18) in their study found 80% uptake rate with temporalis fascia. Quraishi et al reported success rate of 94% in 32 cases of primary myringoplasty with tragal perichondrium.

Palva et al (1987) in their study of 165 cases of myringoplasties, carried out surgery only when the ear was dry for at least 3 months and reported success rate was 96%. Gibb ag, ChangSk et al. (1982) in their study of 206 cases of underlay myringoplasty found the uptake rate of 91.4% for dry ear and 80.9% for wet ear. Gershoff m et al. (1995) found the state of middle ear at the time of operation influences surgical outcome; wet ear have higher rate of reperforation. Brown C et al. (2002) in their study of 165 cases of myringoplasty found success rate of 75% if perforation is dry and 64 % if perforation is wet.

In our study of 40 cases of tympanoplasty all cases had dry ear preoperatively atleast for 6 weeks hence overall graft uptake rate was 82.5%, which correlates well with the quoted literature. Infections transmitted along the eustachian tube or external auditory canal would contribute significantly for the graft failure.

**Hearing result**

87.5% of cases showed improvement in hearing, while 12.5% of them showed no improvement after three month follow-up period. About 90% cases operated with temporalis fascia as graft material showed hearing improvement, while similar percentage (85%) of cases who were operated using tragal perichondrium showed improvement in hearing (statistically not significant p>> 0.05) as shown in the table-6. Mean improvement in hearing using temporalis fascia was 10.50 db and that with tragal perichondrium was 09.0db (statistically not significant p>>0.05) as shown in table -7. Jyoti P. Dabholkar (2007) reported hearing result in total 50 patients, that 76% of patients in temporalis fascia group showed improvement while tragal perichondrium group achieved 75% hearing gain. This study also compares well with Sunita Chhapola, Inita Matta (2011) whose postoperative hearing assessed after 6 months of surgery reported that temporalis fascia graft showed air bone gap of less than 10db in 82% of patients and more than 10db in 18% patients, air bone gap with tragal perichondrium was less than 10 db in 78% of patients and more than 10db in 22% of patients. Our results also compared well with Ophir et al. (1987), Terry RM (1988), result with fat myringoplasty.

**Factors affecting graft take-rate**

The uptake rates were quite comparable for all size and site of perforations in our study. Similar opinion were expressed by Blanshardjd et al (1990), who opines that age at operation, size of perforation and prior adenoidectomy had no significant influence on the success rate or audiological outcomes. In our study like most of the previous studies, results were not dependent on size and site of perforation. Similar opinions were expressed by other surgeons in different studies that age of patient and size had no significant influence on success rate. Preoperative dry ear should be considered for better results (5,24). Berger g, et al (1997), stated in their study that results of myringoplasty were independent of patient’s age ,sex, location and size of perforation.
Low socioeconomic status, poor personal hygiene and poor nutritional status might also contribute towards graft rejection in our study.

CONCLUSION
Both temporalis fascia and tragal cartilage perichondrium can be considered as graft material. Graft uptake rate and hearing improvement were comparable in both grafts but slightly better hearing improvement is seen in case of better in temporalis fascia graft as compared to perichondrium graft. Success rate is not dependent on size and duration of perforation but ears must remain dry for at least 6 weeks prior to operation.

REFERENCES