ABSTRACT

Background: Chronic otitis media is an inflammatory process of the mucoperiosteal lining of the middle ear space and mastoid. The main aim of surgery of chronic ear disease is to eliminate disease process and to give the patient a dry safe and functioning ear. Interlay myringoplasty a newer technique has shown promising results with higher success rates than other conventional methods of myringoplasty. We aimed to study the hearing gain in terms of air bone gap and outcome of graft uptake.

Materials & methods: This is a prospective study of 18 months duration from January 2013 to June 2014 carried out in ninety (90) patients of chronic suppurative otitis media (CSOM) with large central perforation (more than 50% of tympanic membrane). All patients underwent through interlay myringoplasty after clinical examinations, audiometric tests & routine investigations. Patients were called for regular follow up for 16 weeks.

Results: Pre operatively mean air bone gap was 27.50 ± 5.53 dB. Post operatively after 16 weeks mean air bone gap was 13.67 ± 5.56. On last follow up at 16 weeks, maximum numbers of graft rejections were observed in 6 patients (6.7%). Success rate was 93.3%.

Conclusion: Myringoplasty is a safe and effective technique to improve the quality of life of patients. The interlay technique had a better graft take up and hearing improvement and also showed promising results in terms of limited follow up period and limited number of cases involved.

Keywords: Interlay, Myringoplasty, Air bone gap, CSOM.

INTRODUCTION

Perforation of the tympanic membrane primarily results from middle ear infections, trauma or iatrogenic causes. Up to 80% of these perforations heal spontaneously (Galdstone et al., 1995)[1]. Myringoplasty is a surgical technique used to restore the integrity of tympanic membrane and to improve hearing level (Aslam and Aslam, 2009)[2]. It was introduced by Berthold (1878)[3].

Repair of eardrum by doing myringoplasty may confer considerable benefits to patients with tympanic membrane perforation. These benefits include prevention from middle ear infections, aural discharge and improvement in hearing along with protect against long-term middle ear damage by preventing the ossicular pathology. It also prevents migration of squamous epithelium around the margins of perforation with possible consequent cholesteatoma formation (Bluestone et al., 1979)[4].

Many techniques of myringoplasty are described in the literature. A few of the numerous techniques include Underlay (Shea, 1960)[5], Overlay (House,
Although different types of grafts such as autogenous, homologous and allografts have been attempted for performing Myringoplasty but temporalis fascia graft remains the mainstay of almost all the procedures of Myringoplasty having advantages of its physiological similarity with tympanic membrane (Sheehy, 1973; Komune et al., 1992; Schwab, 1986; Eavey, 1998; Fernandes, 2003; Juvekar, 1999; Huang et al., 2004; Karlan, 1979; Schwaber, 1986; Eocudero et al., 1979; Schwaber, 1986; Juvekar, 1999; Komune et al., 1992; Fernandes, 2003; Juvekar, 1999; Huang et al., 2004; Karlan, 1979; Eocudero et al., 1979) techniques. Although each technique is improvised version of the other technique yet the choice of technique is mostly dependent on the surgeon’s familiarity with the particular procedure. No doubt, in such a scenario, it is difficult to claim the relative superiority of a single technique.

Out of the myriad of various myringoplastic procedures in Interlay technique the graft is placed between inner endothelial layer and middle fibrous layer of tympanic membrane. From the point of view of access, Interlay technique is also considered to be better as getting an interlay plane (between the fibrous layer and mucosa) is easier and faster. Moreover, it has no fear of residual epithelium. The Interlay myringoplasty approach has shown promising results with success rates higher than 90% (Komune et al., 1992; Guo et al., 1999; Vishal, 2006; Hay and Blanshard, 2014)

AIM & OBJECTIVES:

To assess Interlay myringoplasty procedure in cases of chronic suppurative otitis media with inactive mucosal disease in large central perforation. This aim was fulfilled with the help of following objectives:

1. Hearing gain in terms of air bone gap.
2. Outcome of graft uptake.

MATERIALS & METHOD:

This is a prospective study of 18 months duration from January 2013 to June 2014 on ninety (90) patients of chronic suppurative otitis media (CSOM) with large central perforation (more than 50% of tympanic membrane) in the age group of 16 - 49 years conducted in Era’s Lucknow Medical College & Hospital (ELMCH). Ethical committee approval had been taken.

Patient included were cases of safe CSOM with pure conductive hearing loss, age ranging from 16-49 years of both male & female, having dry ear (no discharge for at least four weeks) and patients with all follow-up of 4 months.

Patient excluded from the study were patients with active foul smelling discharge, vertigo, tinnitus, granulation or cholesteatoma, those having Sensorineural hearing loss or mixed hearing loss, cases with tympanosclerosis, revision or combined procedures (mastoidectomy and ossiculoplasty), any deformity or congenital anomaly of external ear, unusual infections such as Malignant otitis externa and complication of chronic ear diseases (Meningitis, Brain abscess, Lateral sinus thrombosis), active focus found in the nose, sinuses or throat. Patients with inadequate follow up were excluded from the study.

Pre-operatively all patients had a pure tone audiogram with an average of four frequency (0.5/1/2/4 kHz) calculated for both air conduction and bone conduction. Post-operatively a pure tone audiogram using (0.5/1/2/4 kHz) was performed at 4 months (last) follow-up. Tuning fork tests should be done on all patients to confirm the audiologic findings.

Interlay myringoplasty in all cases was carried under general anesthesia (GA) by same surgeon. Post auricular approach was used and temporalis fascia used as a graft material in every case. Karl-Zeiss operating microscope was used in all surgeries using proper magnification.

(Fig 1). Postauricular region and four quadrants of the cartilaginous external auditory canal were injected with 2% lidocaine with 1:100,000 epinephrine solution.
for vasoconstriction. The auricle and external auditory canal was flushed with povidone-iodine [Betadine] solution and then sterile saline.

A postauricular Wilde’s incision was made about 3 mm behind the postauricular crease using a 15 No. scalpel blade. Temporalis fascia graft was harvested. Periosteal flap was elevated.

After meatotomy Mollison’s self retaining haemostatic mastoid retractor was applied. Margins of the remnant tympanic membrane were freshened. Vascular strip incision given and tympanomeatal flap was elevated. In Interlay technique fibro-squamous layer the remnant tympanic membrane along with the annulus was elevated leaving behind the mucosal layer and the temporalis fascia graft was placed between fibrous layer and the endothelial (mucosal) layer the drum remnant (Fig 3). Very few gelfoam pledgets soaked in an antibiotic ear drop solution, placed in middle ear cavity. The ear canal was packed with gelfoam pledges soaked in an antibiotic eardrop solution. The periosteal incision was closed with 3-0 absorbable suture (Vicryl). The postauricular incision is approximated with absorbable suture in an interrupted simple fashion using a subcuticular closure. A cotton ball is placed in the meatus and a mastoid dressing is applied. On the day of surgery patient was kept on IV antibiotics (Ceftriaxone) and analgesics.

Patients were discharged on the next day of surgery with same mastoid dressing. They were advised oral antibiotics for 2 weeks (amoxycillin-clavulenic acid) thrice a day along with oral antihistamine (levocetrizine 2.5mg) and diclofenac sodium 50 mg given twice a day. Mastoid dressing stitches were removed on 7th postoperative day and endomeatal cotton was also removed. After this Antibiotic ear drop containing ofloxacin and dexamethasone were started and continued for next 3 weeks.

Follow Up of the patients done weekly in first operative month, biweekly for next two month followed by final visit after four month. At every follow up patients were examined under ear microscopy (EUM) to assess the graft uptake and complication (if any) at every follow up visit. In the last follow up visit pure tone audiometery (PTA) was done and compared with pre operative air bone gap to evaluate the hearing improvement.

**Change in Hearing Status:** For the purpose of evaluating the change in hearing status, the following criteria were used: AB Gap of:

1. 0 to 20 dB - Successful
2. >20 dB/Graft rejection – Failure

Results were tabulated and statistical analysis was done using statistical software. Paired t test was applied...
for the statistical analysis of pre-operative and post-operative air-bone gap. Comparison in various groups was done by using two sample t test for proportion.

RESULTS:

The study was carried out on ninety patients at ELMCH, Lucknow in the period from January 2013 to June 2014. The minimum age of a patient in the study was 16 years and the maximum was 49 years. Pre operatively air bone gap ranged from 20 to 35 dB. Out of total ninety patients 50% had air bone gap of 30 dB or more, 26.7% had air bone gap of 25 dB and 23.3% had air bone gap of 20 dB. Mean air bone gap was 27.5 dB. (Table 1)

Post operatively on 28th day, fourth follow up maximum number of graft rejections were observed in six (6) patients (6.7%) while graft accepted in eighty four (84) patients. (Table 2) Majority of cases had air bone gap within 20 dB (86.7%), 25dB (10%) and 30 dB (3.3%). Mean air bone gap was 13.67±5.56. (Table 3) The significant mean reduction in air bone gap was observed. Statistically, difference in reduction in air bone gap was significant (p<0.0001). (Table 4) Success rate was 93.3%. (Table 5)

Table 1: Shows Pre Operatively air bone gap

<table>
<thead>
<tr>
<th>Parameter/ Variable</th>
<th>Interlay Myringoplasty (n=90)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td>≤20 dB</td>
<td>21</td>
</tr>
<tr>
<td>21-25 dB</td>
<td>24</td>
</tr>
<tr>
<td>26-30 dB</td>
<td>24</td>
</tr>
<tr>
<td>31-35 dB</td>
<td>21</td>
</tr>
<tr>
<td>Mean±SD</td>
<td>27.50±5.53</td>
</tr>
</tbody>
</table>

Table 2: Shows Graft rejection at fourth follow up (28 days)

<table>
<thead>
<tr>
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<th>Interlay Myringoplasty (n=90)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td>Graft rejection</td>
<td>6</td>
</tr>
</tbody>
</table>

Table 3: Shows Post Operatively air bone gap at last follow up (16 weeks)

<table>
<thead>
<tr>
<th>Parameter/ Variable</th>
<th>Interlay Myringoplasty (n=90)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td>≤10 dB</td>
<td>51</td>
</tr>
<tr>
<td>11-15 dB</td>
<td>27</td>
</tr>
<tr>
<td>16-20 dB</td>
<td>0</td>
</tr>
<tr>
<td>21-25 dB</td>
<td>9</td>
</tr>
<tr>
<td>26-30 dB</td>
<td>3</td>
</tr>
<tr>
<td>Mean±SD</td>
<td>13.67±5.56</td>
</tr>
</tbody>
</table>

Table 4: Shows change in air bone gap in last follow up (16 weeks)

| Group | Preoperative | Post-operative | Change | Significance of change (Paired t test) | |
|-------|--------------|----------------|--------|---------------------------------------|
| Mean | SD | Mean | SD | Mean | SD | t' | p' |
| Interlay Myringoplasty | 27.50 | 5.53 | 13.67 | 5.56 | -13.83 | 8.88 | 16.73 | <0.0001 |

Table 5: Shows Outcome of graft uptake at last follow up (16 weeks)

<table>
<thead>
<tr>
<th>Parameter/ Variable</th>
<th>Interlay Myringoplasty (n=90)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td>Failed</td>
<td>6</td>
</tr>
<tr>
<td>Successful</td>
<td>84</td>
</tr>
</tbody>
</table>

Table 6: Success rate for Interlay Technique (Graft take) as reported in different case series.

<table>
<thead>
<tr>
<th>SN</th>
<th>Author (Year)</th>
<th>No. of cases</th>
<th>% Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Komune (1992) 8</td>
<td>69</td>
<td>94.2</td>
</tr>
<tr>
<td>2.</td>
<td>Guo et al. (1999) 16</td>
<td>59</td>
<td>96.2</td>
</tr>
<tr>
<td>3.</td>
<td>She et al. (2008) 23</td>
<td>30</td>
<td>87.5</td>
</tr>
<tr>
<td>4.</td>
<td>Hay and Blanshard (2014) 18</td>
<td>116</td>
<td>91</td>
</tr>
<tr>
<td>5.</td>
<td>Patil et al. (2014) 24</td>
<td>100</td>
<td>96.0</td>
</tr>
<tr>
<td>6.</td>
<td>Present study (2016)</td>
<td>90</td>
<td>93.3</td>
</tr>
</tbody>
</table>
DISCUSSION:

Chronic suppurative otitis media (CSOM) is the result of an initial episode of acute otitis media and is characterized by a persistent discharge from the middle ear through a tympanic perforation. It is an important cause of preventable hearing loss, particularly in the developing world. According to a WHO report, India is amongst the nations with highest burden of CSOM (WHO, 2004)[19].

Tympanoplasty and/or Mastoidectomy are frequently necessary to permanently cure CSOM and rehabilitate hearing loss patients. These procedures are readily available in tertiary centres with an otologic department, a standard service in all developed countries and is also recommended in national programme for deafness in our country. Tympanoplasty involves closure of the tympanic perforation by a soft tissue graft with or without reconstruction of the ossicular chain. Mastoidectomy involves removing the mastoid air cells, granulations, cholesteatoma and debris using bone drills and microsurgical instruments. Sequential destruction of the malleus, incus and stapes requires progressively more medially placed tympanic grafts. The extent of damage to the ossicular chain determines the specific types of tympanoplasty; Tympanoplasty is classified as type I, II, III, IV and V. Among these, Type-I Tympanoplasty or Myringoplasty is the simplest operative procedure performed to repair the perforation in ear drum by repairing the tympanic membrane only. It is performed when only except for ear drum, the entire ossicular chain is intact (Wullstein, 1953)[20]. Myringoplasty is a beneficial procedure to protect the middle ear and inner ear from future deterioration and also gives improvement in hearing after surgery[21].

Although myringoplasty involves simple closure of tympanic membrane, however, there are at least a dozen approaches to perform this procedure such as Underlay, Overlay, Inlay, “Gelfilm Sandwich”, “Swinging Door”, Triple “C”, Double breasting, Anterosuperior anchoring and Laser assisted “spot welding”. Among these for the last few years, a newer technique Interlay is gaining popularity and is being successfully used with promising results.

For this purpose, a total of ninety patients of chronic suppurative otitis media with inactive mucosal disease in large central perforation were enrolled in the study. Selection of inactive mucosal disease was done because active disease might have active infection which might confound with the results. Temporalsis fascia was used as a graft material because it is easy to take; large surface area is available, has a low metabolic rate and does not require special preparation[22,23].

Pre-operative air bone gap ranged from 15 dB to 35 dB with a mean value ranging from 27.50±5.53. All the patients had unilateral disease and having air bone gap indicating fair to poor hearing status, thus indicating the need for surgical intervention for all the patients.

In all the cases, a unilateral procedure was performed. Total 6 (6.7%) rejections took place and all of them within 14 days. No new rejection took place in subsequent follow up period up to 16 weeks after surgery. Not any other complication noticed in any of the patient during follow up period.

On evaluating the air bone gap at final follow up interval was observed to be 10 dB in majority of cases (56.7%). Mean air bone gap 13.67±5.56 dB (Table 3). Eventually, the success rate was 93.3%.

The results of Interlay technique were in close proximity with the results obtained by Komune et al. (1992)[8] who observed a success rate of 94.2% for Interlay technique. Interlay technique reportedly has a high success rate. A comparative account of success rate for interlay technique as reported in various studies is shown in Table 6.

It could be seen that all the studies, including the present study the success rates for Interlay technique have been quite promising, generally above 90%. The better graft take in Interlay method is that it provides support to graft from both the sides.

However, given the number of studies and result of Interlay myringoplasty, we find that it is not as much popular. The reason for its lower popularity is that it requires additional skill and it time consuming. Preparation of margins for interlaying and tactical positioning of the graft needs precise handling and manipulation of the graft and hence they are generally attempted in a setup with adequate technical and physical infrastructure.

As far as air bone gap resolution is concerned, the results shown are variable in different studies for different techniques. However, Patil et al. (2014)[24]
their series of 100 cases who were approached using Interlay method showed a phenomenal reduction in air bone gap from a pre-operative mean value of 36.42±12.0 dB to 9.7±6.71 dB, thus showing a reduction of almost 26.72 dB.

In accordance with the observations in these studies, we found post-operative air bone gap up to 10 dB in majority (56.7%) of cases. A better air bone gap reduction in Interlay method is mainly possible owing to its better conductive efficacy. Owing to the flap’s position between two interlaying layers the frequency loss is controlled and that is the reason for a better conduction and reduced air bone gap. There is also no risk of lateralization or medialisation of the graft due to well supported by fibro-squamous layer laterally and mucosal layer medially. The findings in present study showed a better graft take in Interlay method which coupled with a better post-operative air bone gap provided a better overall outcome. As compared with other method of myringoplasty Underlay technique shows in previous studies of outcome of 85.7% in Guo et al (1999)[16], 88.8% in Crovetto et al (2000)[25], 87% in Ullah et al (2008)[26], 81% in Sheikh et al (2009)[27], 88.6% in Baloch et al (2012)[28] and 90% in Sharma & Saroch (2013)[29] respectively. While Overlay technique in previous studies shows outcome of 55% in Ullah et al (2008)[26] and 74.4% in Rehman et al (2011)[30].

CONCLUSION:

Myringoplasty is a safe and effective technique to improve the quality of life of patients, avoiding continuous infections and allowing them contact with water. The present study showed that although Interlay technique requires additional expertise in surgery it gives better graft uptake and hearing improvement. Above findings in present study substantiate the results obtained in some recent studies. However, there is paucity of comparative literature on the issue.

The advantage of Interlay myringoplasty is that neither lateralization of tympanic membrane nor blunting of the anterior tympanomeatal angle was observed. This means lower complications and thus Interlay myringoplasty is an effective surgical technique over conventional methods for closure of perforation and hearing gain (audiological improvement) in large central tympanic membrane perforation in cases of chronic suppurative otitis media (CSOM) with inactive mucosal disease.

DISCLOSURES:
a) Competing interests/Interests of Conflict- None
b) Sponsorships – None
c) Funding - None
d) Written consent of patient- taken
e) Animal rights-Not applicable.

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