

# Type I Tympanoplasty in patients with Chronic Suppurative Otitis Media: Does it improve hearing significantly?

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## ABSTRACT

**Aim:** To determine the improvement in hearing after type I Tympanoplasty in patients with chronic suppurative otitis media.

**Methods:** This descriptive case series conducted in the Department of ENT, Sh. Zayed Hospital, Lahore during one year from 01-01-2019 to 31-12-2019.. Non-probability consecutive sampling technique was used.

**Results:** The mean age of patients was 32.91 years (standard deviation  $\pm 6.22$ ). There were 32 (49%) male patients and 33 (51%) female patients with male to female ratio 0.96:1. The mean of disease duration was 33.29 months (standard deviation  $\pm 26.53$ ). There were 37 (57%) patients who had  $<40$ dB air bone gap before surgery and 28 (43%) patients had  $>40$ dB air bone gap before surgery. The mean air bone gap before surgery was 42.08 dB ( $\pm 6.84$ ) and after surgery was 28.77 dB (standard deviation  $\pm 8.19$ ). Most of the patients 56 (86%) had significantly improved hearing after tympanoplasty which is statistically highly significant ( $p < 0.001$ ) and only 9 (14%) patients had no improvement

**Conclusion:** It is found in this study that with underlay technique used for type-1 tympanoplasty, good anatomical and functional outcome can be achieved with appropriate skills and experience.

**Keywords:** Tympanic Membrane Perforation, Air Bone Gap, Tympanoplasty.

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## INTRODUCTION

Tympanic membrane (TM) perforation is a common condition seen in ENT practice which is usually seen as a result of otitis media and trauma or rarely as a complication of ear surgery like myringotomy and grommet insertion<sup>1</sup>.

Chronic suppurative otitis media (CSOM) is a chronic inflammation of the middle ear cleft mucoperiosteal lining, characterised by discharge from the ear, permanent perforation of the tympanic membrane and hearing impairment. It is a significant cause of deafness in the world<sup>2</sup>. It is estimated that the prevalence of tympanic membrane perforation is between 1-3% of the general population<sup>3</sup>.

Tympanoplasty is now a proven surgery that otorhinolaryngologists around the world routinely perform for closure of tympanic membrane perforations<sup>4</sup>. Tympanoplasty is a procedure performed to repair a tympanic membrane perforation with or without reconstruction of ossicular chain after eradicating all the disease in the middle ear cleft<sup>5</sup>. Type 1 tympanoplasty is performed when there is only perforation of the tympanic membrane and the ossicular chain is healthy<sup>6</sup>. It was first defined in 1952 by Wullstein and Zollner as a method of tympanic membrane reconstruction. Since then, several methods and graft materials have been used for repairing the tympanic membrane. The material used most widely is the fascia temporalis<sup>7</sup>. The 'overlay' and 'underlay' techniques are the two most commonly applied methods for the positioning of graft in relation to residuals of both; tympanic annulus and membrane. Precisely, Underlay method is a simple, time effective and has high success rate. It is the most frequently performed technique because

of these benefits<sup>8</sup>.

Although generally favourable, the outcomes of tympanic membrane repair may differ significantly based on multiple factors, including infection, size of the perforation, age of the patient, eustachian tube dysfunction, experience of the surgeon and operative procedure variations<sup>9</sup>.

The primary objective of Type I tympanoplasty remains the same: permanent closure of the tympanic membrane (TM) to prevent recurrent middle ear infections and to restore the eardrum to the ossicular chain for optimum sound energy coupling, resulting in improved hearing and thus enhancing the quality of life of patients<sup>10</sup>.

Success of tympanoplasty type 1 is directly related to improvement in hearing quality which can be assessed by subjective auditory behaviour and objective auditory behaviour relative to audiometric results<sup>11</sup>.

Several researchers have used a number of methods to document postoperative hearing evaluation in the literature and mostly used parameters are average hearing attainment, post-surgical hearing, and air-bone gap. "Hearing improvement" is mostly defined as the hearing level obtained as more than 10 or 20dB, or air-bone gap decrease to within 10, 20, or 30 dB or satisfactory gain of social hearing.

According to the International Organization for Standardization, the workable hearing level is an average of 40 dB or better over the speech frequencies. For patients, socially adequate hearing is the most significant end result. As an indicator of postoperative hearing performance, the American Academy of Ophthalmology and Otolaryngology recommends average hearing gain at frequencies of 500-2000 Hz, or a decrease in air-bone

gap<sup>12</sup>.

Few studies have been conducted on reduction of air bone gap after type I tympanoplasty with insignificant results. Most of the international and local studies have been conducted on graft uptake, whereas this study has focused on the reduction of air bone gap after the operation which has not been studied before in Pakistan.

This study will help to determine the effectiveness of type I tympanoplasty in reducing air bone gap and document the improvement in hearing of patients with chronic suppurative otitis media three months after surgery. The results from this study will help in setting up guidelines for improvement in this procedure or using an alternate in case we get unsatisfactory results.

## METHODOLOGY

This descriptive case series conducted in the Department of ENT, Sh. Zayed Hospital, Lahore during one year from 01-01-2019 to 31-12-2019.. Non-probability consecutive sampling technique was used. The estimated sample size for this study was 65 cases by using the confidence level 95%, margin of error as 9% and 85.88% improvement in air- bone gap against criteria of improvement 10dB after treatment.

### Inclusion criteria

- Age: 20 to 50 years
- Gender: Both
- Patients with CSOM (with at least 3 months history of ear discharge).
- Air bone gap  $\geq$  25dB.

### Exclusion criteria

- Patients with active ear discharge through a perforated tympanic membrane, diagnosed by consultant on otoscopy.
- Patients with otitis externa or otomycosis diagnosed by consultant.
- Patients with cholesteatoma (pearly white keratin debris at attic) known as attic- antral disease, diagnosed by consultant.
- Patients with mastoiditis, as determined by x-ray mastoid.
- Patients with sensorineural hearing loss diagnosed on pure tone audiometry.

**Data collection procedure:** After taking ethical approval, the patients who fulfilled the selection criteria were recruited in study after getting informed consent from indoor and OPD, ENT Department, Sheikh Zayed Hospital, Lahore. All patients with chronic suppurative otitis media (tubo-tympanic disease) having hearing loss were examined by tuning fork tests and pure-tone audiometric testing. All the data was gathered in Performa. Pure tone audiometry was performed by a consultant audiologist one week before surgery and after three months of surgery. Improvement at three months was labeled as per operational definition.

All patients went through procedure under general anesthesia. End aural incision was used. Temporalis fascial graft was taken. Edges of perforation were freshened. Adequate tympanometal flaps were raised depending on the site and size of perforation. Middle ear mucosa and ossicles were inspected. Gel foam was placed

on the promontory. An underlay temporalis fascia graft was placed and positioned carefully to ensure the complete closure of the perforation. It was covered with the pieces of gel foam. Small Bismuth iodoform paraffin paste (BIPP) pack was placed over gel foam. Ear canal was lightly packed with another BIPP pack. Skin incision was closed with 4-0 prolene. Head bandage was done. Patients were given intravenous antibiotics for 24 hours. Postoperatively facial nerve was checked. Tuning fork tests were done. Head bandage was removed after 24 hours. Stitches were removed after one week. BIPP pack was removed after two weeks. Patients were followed after two weeks and then after three months when the pure tone audiometry was done.

Data was entered and analyzed in SPSS v. 20. Numerical variables like age, pre- & post-surgery air bone gap were presented as Mean $\pm$ SD. Categorical variables like gender and improvement in hearing were presented as frequency (%).

### Operational definitions:

**Improvement:** Reduction of air bone gap  $>10$  dB, 3 months after type I tympanoplasty as measured by pure tone audiometry.

**CSOM:** Discharging ear  $>3$  months with central perforation of tympanic membrane on otoscopy and air bone gap  $>25$ dB on pure tone audiometry.

**Air Bone Gap:** Air bone gap was measured by pure tone audiometry 3 months after surgery. (Air bone Gap = Bone conduction – Air conduction)

## RESULTS

This study was carried out to assess the reduction in air-bone gap after type-I tympanoplasty in the management of chronic suppurative otitis media of tubo-tympanic variety. Sixty five consecutive cases were selected for this study. The age range was from 20 to 50 years. The mean age of patients was 32.91 years (standard deviation  $\pm 6.22$ ). There were 29(45%) patients from 20-30 years of age, 25(38%) patients between 31-40 years while only 11(17%) patients from 41-50 years of age. The age distribution is shown in Table 1.

There were 32 (49%) males patients and 33 (51%) patients were female with male to female ratio 0.96:1 (Table 2).

Table 3 shows the frequency of duration of ear discharge in months. There were 23 (35%) patients who had ear discharge of 7-22 months duration and 42 (65%) patients who had ear discharge of more than 22 months duration. The mean duration of ear discharge was 33.29months (standard deviation  $\pm 26.53$ ).

There were 37 (57%) patients who had  $<40$ dB air bone gap before surgery and 28 (43%) patients had  $>40$ dB air bone gap before surgery. The mean air bone gap before surgery was 42.08 dB (standard deviation  $\pm 6.84$ )(Table 4).

There were 43 (66%) patients who had  $<40$ dB air bone gap after surgery and 22(34%) patients had  $>40$ dB air bone gap after surgery. The mean air bone gap after surgery was 28.77 dB (standard deviation  $\pm 8.19$ ) (Table 5). Table 6 shows the frequency of improvement of patients. Most of the patients 56(86%) were improved after type 1

tyimpanoplasty which is statistically highly significant (p <0.001) and only 9(14%) patients had no improvement. Table 7 shows the stratification of Improvement According to Age of Patients. Between 20-30 years of age, 26(40%) patients showed improvement in air bone gap after surgery and 3 (5%) had no improvement. Between 31-40 years of age, 21(32%) patients had improved and only 4(6%) patients had no improvement. Between 41-50 years of age, 9(14%) patients improved and only 2 (3%) patients had no improvement.

Table 8 shows the stratification of improvement according to sex of patients. Most of the male patients were improved 25 (38%) and similarly most of the female patients were also improved 31(49%). Only 7(10%) male patients were not improved while only 2 (3%) female patients were not improved with a p value of 0.065 which is statistically not significant.

Table 9 shows the stratification of improvement according to duration of ear discharge in months. Patients with 7-22 months duration of ear discharge, 20 (31%) patients were improved and only 3(5%) had not improved. Patients with more than 22 months duration of ear discharge, thirty six (55%) patients were improved and only 6 (9%) patients had not improved with a p value 0.69 which is statistically not significant.

Table 10 shows the stratification of air bone gap before and after surgery. There were 31 (48%) patients improved before surgery and 6 (9%) patients had no improvement <40 dB and 49(75%) patients were improved after surgery and only 5(8%) patients had no improvement. More than 40dB there were 25(38%) improved before surgery and only 3(5%) patients had no improvement while after surgery 7(41%) patients had improvement and only 4(6%) had no improvement which is statistically not significant p value (0.06).

Table 1: Age Distribution of Patients (n=65)

Age in years	n	%age
20 – 30	29	45.0
31 – 40	25	38.0
41 – 50	11	17.0
Mean ± SD	32.91± 6.22	

Table 2: Sex Distribution of Patients

Gender	n	%age
Male	32	49.0
Female	33	51.0
Male to female ratio	0.96:1	

Table 3 Frequency of duration of Ear discharge in months

Duration of ear discharge in months	n	%age
7 – 22	23	35.0
>22	42	65.0
Mean ± SD	33.29±26.53	

Table 4 Frequency of Air Bone Gap Before Surgery

Before surgery (dB)	n	%age
<40	37	57.0
>40	28	43.0
Mean ± SD	42.08±6.84	

Table : Frequency of Air Bone Gap After Surgery

After surgery (dB)	n	%age
<40	43	66.0
>40	22	34.0
Mean ± SD	28.77±8.19	

Table 6: Frequency of Improvement of Patients

After surgery (dB)	n	%age
Yes	56	86.0
No	9	14.0

Table 7: Stratification of Improvement According to Age of Patients

Age	Improvement		p-value
	Yes	No	
20 - 30	26 (40%)	3 (5%)	0.83
31 – 40	21 (32%)	4 (6%)	
41 - 50	9 (14%)	2 (3%)	

Table 8: Stratification of Improvement According to Sex of Patients

Gender	Improvement		p-value
	Yes	No	
Male	25 (38%)	7 (10%)	0.065
Female	31 (49%)	2 (3%)	

Table 9: Stratification of improvement according to duration of discharge in months

Duration of Ear discharge in months	Improvement		p-value
	Yes	No	
7 – 22	20 (31%)	3 (5%)	0.69
>22	36 (55%)	6 (9%)	

Table 10: Stratification of air bone gap before and after surgery

Air bone gap	Before surgery		After surgery	
	Yes	No	Yes	No
<40	31 (48%)	6 (9%)	49 (75%)	5 (8%)
>40	25 (38%)	3 (5%)	7 (11%)	4 (6%)

## DISCUSSIONS

From last 2-3 centuries, several trials have been done to close the perforation in tympanic membrane. This may occur as a consequence of chronic media otitis. Besides ear discharge, this perforation can also cause the significant hearing loss<sup>13</sup>. Tympanoplasty is a common surgical procedure for chronically discharging ears and it may be performed with or without mastoidectomy<sup>14</sup>. In 1950, tympanoplasty surgery was applied and various techniques and graft materials were used <sup>15</sup>. Type-I tympanoplasty is as similar as myringoplasty and is applied to repair the perforated tympanic membranes without any modification in ossicular system<sup>16</sup>.

The main objective of this procedure is to minimize infection, to prevent recurrent ear discharge and to improve hearing<sup>17</sup>. Our study focused on hearing improvement aspect after type 1 tympanoplasty. In our study, mean age of patients was 32.91±6.22 years. Mostly, [54(83%)] patients were aged between 20--40 years. In a study done by Patil, there were 29(24.16%) patients in 21-30 years age group, 23 (19.16%) patients in 31-40 years, 17 (14.16%) patients in 41-50 years and 10(8.33%) patients in 51-60 years. The mean age of patients was calculated as 29.8±12.94 years which was comparable with that calculated in our study<sup>4</sup>. In another study, done in Pakistan by Adnan Saleem Umar, the age of patients was ranged from 21 years to 46 years with mean age of 33.5 years which is also comparable with our study<sup>6</sup>. In another study carried out by Hasaballah the mean age of patients was 24.9±9.5 years, which was comparable with our study<sup>16</sup>. Similar findings were noted in the study of Singh et al, in which the mean age was 28.9 years (range: 13-48 years) which is comparable with our study<sup>18</sup>.

In our study there were 32(49%) male patients and 33 (51%) patients were female with male to female ratio 0.96:1. In a study reported by Hasaballah there were 26 females (66.6%) and 13 males (33.4%) which is comparable with our study<sup>16</sup>. Another study done by Singh 55% (n= 22) were female and 45% (n = 18) which is also comparable with our study<sup>18</sup>.

Regarding the duration of ear discharge, in our study there were 23(35%) patients who had ear discharge for 7 months to 22 months while 42(65%) patients had ear discharge for more than 22 months was 33.29±26.53 months. This is less than a study carried out by Sayed M. S. Kadah, in which the mean duration of ear discharge was 7.24±3.80 years<sup>1</sup>. In another study carried out by Muhammad Azeem Aslam mean duration of ear discharge was 10.3±6 years<sup>8</sup>.

A 250Hz-8kHz Pure tone audiogram was done before surgery and after three months of surgery. The mean pre-surgical air-bone gap was 42.08 ± 6.84 dB, while 28.77±8.19 dB after three months of surgery (p<0.001) which is statistically significant. There was 31.6% decrease in the air-bone gap. These findings were comparable to the study done by Hasaballah et al who showed that the mean pre-surgical pure tone audiometry - air-bone gap was 26.0±4.4 dB, which was reduced to 13.8±5 dB after surgery pure tone audiometry - air-bone gap (p<0.001) and there was 46.6% decrease in the air-bone gap<sup>16</sup>.

In our study, average air bone gap improvement was 13.3 dB. Our results are similar to Dornhoffer's type I tympanoplasty results (average air bone gap improvement of 11.3±9.2dB)<sup>19</sup>. Our results are also comparable to a study by Patil, who reported a mean improvement in air-bone gap of 10.34±4.68 dB<sup>4</sup>. Similarly Mohamed M. El-Sheikh reported a mean preoperative air-bone gap of 30.6±8.6 dB and the mean postoperative air-bone gap was 15.9±8.7 dB which has shown a highly significant gain in decreasing air-bone gap post-operatively (average air bone gap improvement was 14.7 dB) (P=0.038)<sup>20</sup>. A similar study carried out by Nemade the average air-bone gap which was 43.6 ± 4.4 dB preoperatively which is comparable with this study and improvement in air-bone gap was 22.5 ± 3.5 dB postoperatively which is better than our study<sup>21</sup>.

In our study out of 65 cases, there was improvement in 56 (86%) cases while only 9(14%) had no improvement which is statistically highly significant (p <0.001). In a study carried out by Adnan Saleem Umar, the improvement in the hearing was observed in around 85.9% patients with significant decrease in the air-bone gap after 3 months of surgery which is comparable with our study<sup>6</sup>. Our results are slightly better than studies carried out by Rasha and Razzak which showed an overall hearing threshold improvement in 80.4% and 77% of patients' respectively<sup>22,23</sup>.

In order to have better results in tympanoplasty, proper case selection, (including age, infection) with skill and ability to handle the tissues gently are the main factors. The complications may occur, but most of the complications can be avoided by taking deep care to clean operative environment and procedure, anatomical landmarks and working out with good clinical judgment intra-operatively. Ear should be perfectly dry before tympanoplasty. The infection is a poor prognostic factor. It should be treated by proper antibiotic cover pre and

postoperatively. Prolonged duration of perforation may rise the risk of poor functional outcome.

## CONCLUSIONS

It is found in this study that with underlay technique used for type-1 tympanoplasty, good anatomical and functional outcome can be achieved with appropriate skills and experience. A significant improvement in hearing can be achieved by this surgery.

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