A study on tympanoplasty with or without canaloplasty

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Abstract  

Background: Chronic otitis media is a highly prevalent disease in developing as well as developed countries, causing hearing disabilities to the patients and causing huge problems to the patients in their daily routine lives. The patients are routinely advised for tympanoplasties in the specialized centers. Canaloplasties are routinely performed in such patients to get wide exposure while doing tympanoplasties. The present study seeks to determine the impact of canaloplasty on the outcome of the tympanoplasty.

Material and methods: The study was conducted in Department of Otorhinolaryngology at the Atal Bihari Vajpayee Institute of Medical Sciences and Dr. Ram Manohar Lohia Hospital, New Delhi, between 2018 and 2020, in which 70 patients were included. These patients were randomly divided into two groups. Group A patients underwent type I tympanoplasty with canaloplasty while group B patients underwent type I tympanoplasty alone. Patients in both the groups were followed up with pure tone audiometry and otoscopy at 6 weeks and 12 weeks postoperatively. Hearing was compared in both the groups in terms of air bone gap closure. Air bone gap closure at 12 weeks was considered final. Final analysis was done using SPSS version 21.0.

Results: The patients were randomly divided into two groups. Group A patients underwent type 1 tympanoplasty with canaloplasty, and group B comprises of case I graft tympanoplasty alone. Graft uptake was better in group A with a success rate of 94.3% as compared to group B which had a success rate of 88.57%. Air bone gap closure was better in group A as compared to group B (15.76 dB ± 6.75 v/s 14.87 dB ± 5.99) at 12 weeks postoperatively.

Conclusion: Tympanoplasty with canaloplasty showed advantageous outcome over tympanoplasty alone and thus should be considered with limited exposures. However, the final decision resides with the operating surgeon.

Keywords: Medial graft tympanoplasty, Air bone gap, Canaloplasty, Graft uptake

Introduction

The World Health Organization has estimated that approximately 65 to 330 million people have chronic otitis media (COM) worldwide with 50% having hearing impairment and approximately 28,000 deaths per annum due to complications [1]. COM usually starts with episodes of acute otitis media (AOM) or otitis media with effusion in childhood which results in long-term changes of the tympanic membrane [2]. There is degeneration in the outer and inner fibrous layers of the lamina propria and in the submucosal layer of the tympanic membrane (TM). Such changes reduce the elastic properties of the tympanic membrane making it susceptible to chronic perforations or retraction. Traumatic tympanic perforation can occur from penetrating trauma, blast injuries, and iatrogenic causes [3].

Patients with TM perforations present with ear discharge and hearing loss. As the perforation size increases, transformer ratio diminishes leading to larger canceling effect of sound. Hearing loss almost reaches 40–45 decibel (dB) with total perforation and intact ossicular chain [4].
Wullstein introduced the term “Tympanoplasty” in 1953 [5]. An ideal tympanoplasty aims to restore sound protection for the round window by creating a closed air containing the middle ear and rebuilds the sound pressure transformation mechanism for the oval window [6].

The ear canal plays an important role in modulating the sound that is incident upon the tympanic membrane. A resonance-induced amplification of 20 dB sound pressure occurs in the normal ear canal at frequencies of 2800–3000 Hz owing to the length and diameter of the canal [7]. Thus, canaloplasty should be done till the canal becomes an inverted truncated cone. The secret of the success of the procedure is in the preservation of the canal skin, and to do so, the canal is widened in parts [8].

Thus, the primary objective of the study is to determine the hearing outcome of the patients undergoing tympanoplasty with canaloplasty and without canaloplasty with the secondary objective of comparing the graft uptake in the two groups, keeping the confounding factors to as minimal as possible.

Materials and methods
The present study was conducted in Department of Otorhinolaryngology at the Atal Bihari Vajpayee Institute of Medical Sciences and Dr. Ram Manohar Lohia Hospital, New Delhi, between 2018 and 2020. Institutional ethical was taken prior to the commencement of the study. The study is a prospective study comparing the outcome of hearing in type I tympanoplasty with or without canaloplasty. Patients of age 18–50 years with inactive chronic mucosal otitis media having pure conductive hearing loss (air bone gap of less than or equal to 40 dB) were included in the study. Patients with history of previous ear surgery were excluded. These patients were randomly divided into two groups. Group A patients underwent type I tympanoplasty with canaloplasty, while group B patients underwent type I tympanoplasty alone.

After taking consent, the patients were subjected to detailed history and examination. Preoperative audiometric evaluation was done using the Madsen Astra 2 audiometer. Air bone gap was calculated by averaging the values over 0.5 kHz, 1 kHz, 2 kHz, and 4 kHz frequencies. The patients were then subjected to type I tympanoplasty by a single surgeon. The graft placement was done medial to the handle of malleus in the study. In patients who underwent canaloplasty, the external auditory canal was widened with cutting and diamond burrs removing any canal wall bulge or hump (Fig. 1). Drilling was done along with suction and irrigation (Fig. 2). In case of anterior canal bulge, the canal skin was elevated from lateral to medial till the bony cartilaginous junction 3 mm is lateral to the tympanic annulus, and then using cutting and diamond burrs, the anterior canal bulge was reduced without exposing the temporomandibular joint. The shape of the EAC appears as an inverted cone at the end of canaloplasty (Fig. 3). The aim of the canaloplasty was to expose and visualize the entire tympanic annulus in one view of the microscope.

Patients in both the groups were followed up with pure tone audiometry and otoscopy at 6 weeks and 12 weeks.
postoperatively. Hearing was compared in both the groups in terms of air bone gap closure. Air bone gap closure at 12 weeks was considered final. Final analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0.

Results
A total of 70 patients were included in the current study out of which 35 patients each were included in the group A and group B. Out of 70 patients, 33 were females, and 37 were males. The mean age of the patients in group A was 24.57 ± 5.05, while in group B, it was 28.03 ± 6.71. Chi-square test was done, and the p value was insignificant (0.106).

Similarly, the chi-square value for the distribution of perforation size between the two groups showed p value of 0.951 as seen in Table 1.

The overall mean preoperative air bone gap among 70 patients was 23.03 dB ± 6.87. However, the mean values of the preoperative air bone gap in group A was 22.57 dB ± 7.75, while in group B, the mean value was 23.49 dB ± 5.94. Mann-Whitney test was used to determine the p value for the distribution of air bone gap, and it showed no significant difference between the two groups (p value 0.606). Table 2

Postoperatively, at 12 weeks, in group A, 34 patients (94.3%) showed successful graft uptake, while in group B, 31 patients (88.57%) showed successful graft uptake. The p value for the difference between two groups came out to be 0.356 using Fischer exact test suggesting no significant differences between the two groups.

Postoperative air bone gap closure in group A was 15.76 dB ± 6.75 at 12 weeks. However, air bone gap closure in group B was 14.87 dB ± 5.99 at 12 weeks. The p value for the difference in air bone gap distribution among the two groups at 12 weeks postoperatively was 0.606. The p value was calculated using Mann-Whitney test suggesting no significant between the two groups (Table 3).

Discussion
Tympanoplasty is the surgical procedure in which disease from the middle ear is eradicated followed by the reconstruction of hearing mechanism with or without tympanic membrane grafting [5]. Canaloplasty is a surgical procedure that aims to widen the external auditory canal [8]. Canaloplasty leads to better surgical visualization and hence improved graft uptake. Since the ear canal also plays an important role in modulating sound, thus the study was conducted to determine the additional improvement in hearing on combining canaloplasty with type I tympanoplasty.

In the present study, the confounding factors such as gender and age distribution along with the type of perforation and preoperative air bone gap did not show any significant statistical difference among the two groups.

There are very few studies which compared outcomes of tympanoplasty with or without canaloplasty when

### Table 1
Comparison of size of perforation between group A and group B

| Size of perforation | Group A | Group B | Total | p value |
|---------------------|---------|---------|-------|---------|
| Small               | 7 (20%) | 7 (20%) | 14 (20%) | 0.951 |
| Medium              | 21 (60%) | 22 (62.86%) | 43 (61.43%) |       |
| Large               | 7 (20%) | 6 (17.14%) | 13 (18.57%) |       |
| Total               | 35      | 35      | 70     |         |

### Table 2
Comparison of pre op AB gap (dB) between with and without canaloplasty

| Pre op AB gap (dB) | With canaloplasty | Without canaloplasty | Total | p value | Test performed |
|--------------------|-------------------|----------------------|-------|---------|----------------|
| Mean ± Stdev       | 22.57 ± 7.75      | 23.49 ± 5.94         | 23.03 ± 6.87 | 0.606 | Mann-Whitney test; 569 |
| Median (IQR)       | 22.5 (16.5–30)    | 25 (20–28)           | 24.75 (20–28) |       |                 |
| Range              | 7–35              | 10–35                | 7–35 |         |                 |

### Table 3
Comparison of AB gap closure at 12 weeks between with and without canaloplasty

|                      | With canaloplasty | Without canaloplasty | Total | p value | Test performed |
|----------------------|-------------------|----------------------|-------|---------|----------------|
| Mean ± Stdev         | 15.76 ± 6.75      | 14.87 ± 5.17         | 15.31 ± 5.99 | 0.606 | Mann-Whitney test; 569 |
| Median (IQR)         | 15 (10–20)        | 15 (10–20)           | 15 (10–20) | 0.606 |                 |
| Range                | 5–28              | 5–25                 | 5–28 |         |                 |
the graft is placed medial to the handle of malleus. After 12 weeks postoperatively, the success of graft uptake in group A was better than group B in the current study at 94.3% in group A compared to 88.57% in group B. This corroborates with the earlier studies done by Morrison et al. at the University of Alabama, who reported 91.6% graft uptake in patients with tympanoplasty with canaloplasty as compared to 69% in patients with tympanoplasty alone when the graft was placed medially. However, the success rate of graft uptake was higher in the patients with tympanoplasty with and without canaloplasty, but the p value was not significant in the present study, while it was significant in the study conducted by Morrison et al. [9].

Hearing outcomes at 12 weeks postoperatively showed air bone gap closure of 15.76 dB ± 6.75 in patients with tympanoplasty along with canaloplasty, while the air bone gap closure of 14.87 dB ± 5.99 was seen in patients who underwent tympanoplasty alone. However, in the study conducted by Morrison et al., the air bone gap of 8.7 dB ± 6.3 was seen in patients with medial tympanoplasty with canaloplasty as compared to 14.3 dB ± 11.1 air bone gap in patients with medial tympanoplasty alone, but the difference was statistically significant [9]. Similarly, Virendra et al. in their study had 9 dB improvement in hearing in cases with canaloplasty as compared to tympanoplasty alone [10]. Prakash et al. in their study also achieved 13.48 dB of air bone gap closure in cases with canaloplasty as compared to 11.26 dB air bone gap closure in cases without canaloplasty, and the difference was statistically significant too [11]. This is similar to what we have seen in the current study; however, the difference was not statistically significant with a p value of 0.606.

There are a few studies available which assessed the impact of canaloplasty in hearing outcomes in patients undergoing type 1 tympanoplasty. In the current study, confounding factors were removed as much as possible thus accessing the outcomes more accurately. However, the Eustachian function status is the confounding factor in this study. The results seen in the current study showed similar trends as seen in the previous studies as the percentage of graft uptake and air bone gap closure were better in patients undergoing canaloplasty along with medial graft tympanoplasty as compared to patients undergoing medial tympanoplasty alone.

**Conclusion**

In the nutshell, the present study suggests better outcomes with respect to graft uptake and air bone gap closure in patients who underwent tympanoplasty with canaloplasty as compared to patients who underwent tympanoplasty alone but the difference was not statistically significant. However, the surgical procedures should be decided according to the individuals’ needs of the patient as well as the experience and the skills of the surgeon.

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**Authors’ contributions**

SG collected data of the case series. AK interpreted it. GS wrote it. PK edited it. All authors read and approved the final manuscript.

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**Availability of data and materials**

The datasets used during the current study are available from the corresponding author on reasonable request.

**Declarations**

**Ethics approval and consent to participate**

Ethical approval was taken by institutional ethical committee of ABVMS & RML for the study. Written consent to participate in the study was taken from all patients.

**Consent for publication**

Not applicable.

**Competing interests**

The authors declare that they have no competing interests.

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