



A Comparative Study to Determine Hearing Outcome in Type 1 Tympanoplasty With and Without Canaloplasty in Tubotympanic Type of Chronic Suppurative Otitis Media

Nisha V¹ · K. C. Prasad¹

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Abstract

Background Chronic suppurative Otitis Media is a common ear infection in India. Canaloplasty done with tympanoplasty helps to remove bony overhangs and provide complete visibility of fibrous annulus of tympanic membrane.

Aim 1. To determine the hearing outcome in chronic otitis media (mucosal type) patients undergoing type 1 tympanoplasty with canaloplasty. 2. To determine the hearing outcome in chronic otitis media (mucosal type) patients undergoing type 1 tympanoplasty without canaloplasty. 3. To compare the hearing outcome in the above mentioned 2 groups of patients.

Materials and Methods 56 patients of 15–60 years of age with mucosal type of Chronic otitis media, with central dry perforation and intact ossicles were included in our study. They were divided into group 1 (type 1 tympanoplasty + canaloplasty) and group 2 (type 1 tympanoplasty without canaloplasty), on alternate basis. AC, BC, Air bone gap avg was assessed via pure tone audiometry at 4 frequencies preoperatively and postoperatively at 3rd and 6th month, % closure of ABG average was calculated.

Results Type 1 tympanoplasty along with canaloplasty has better hearing improvement in pure tone audiometry compared to type 1 tympanoplasty alone, as % closure of ABG at postoperative 3rd and 6th month holds significant.

Conclusion The canaloplasty provides better surgical exposure via removing bony overhangs, aids in excellent functional outcome in the form of % closure of ABG. Hence canaloplasty is added as an adjunct to routinely performed aural surgeries to enhance hearing outcome.

Keywords Canaloplasty · Air bone gap · Chronic otitis media · Type 1 tympanoplasty

Abbreviations

AC	air conduction
BC	bone conduction
ABG	air bone gap
% closure of ABG	percentage closure of air bone gap
avg	average

Introduction

Chronic Otitis Media is one of the most common disease of ear in India. Lack of health care, poverty, poor hygiene, overcrowding and ignorance are some of the common risk factors [1, 2]. The exposed middle ear mucosa predisposes to exogenous sources of infection and may produce a conductive hearing loss [1]. Early identification and intervention can prevent the spread of infection, hearing loss and its complications. The site, extent of the disease along with presence of any complications determine the surgical approach to be followed [3]. Tympanoplasty is one of the common ear surgeries performed, to achieve intact neo tympanum with normal hearing function. There are many modifications in this approach. One such is canaloplasty, wherein widening of external auditory canal, helps to remove bony overhangs and provide complete visibility of fibrous annulus

✉ K. C. Prasad
drkcprasad@yahoo.co.in

Nisha V
nishav3394@gmail.com

¹ Department of ENT, Sri Devaraj URS medical college,
563101 Tamaka, Kolar, Karnataka, India

of tympanic membrane. There is a vast literature available on both tympanoplasty and canaloplasty. But there are a very few literature suggesting the impact of canaloplasty when done along with tympanoplasty. Canaloplasty helps in better placement of graft, prevent lateralization of tympanic membrane, promotes hearing improvement. Hence when canaloplasty is done in cases of type 1 tympanoplasty, it will aid in lesser surgical time and better exposure as this will reduce the need for frequent adjustment of microscopic vision in surgical field.

Objectives of the Study

1. To determine the hearing outcome in Chronic otitis media (mucosal type) patients undergoing type 1 tympanoplasty with canaloplasty.
2. To determine the hearing outcome in Chronic otitis media (mucosal type) patients undergoing type 1 tympanoplasty without canaloplasty.
3. To compare the hearing outcome in the above mentioned 2 groups of patients.

Materials and Methods

This prospective comparative study was conducted in patients with Chronic otitis media mucosal type, Department of Otorhinolaryngology, RL Jalappa Hospital and Research centre attached to Sri Devaraj Urs Medical College, Tamaka, Kolar between January 2021 to August 2022. Patients between 15 and 60 years of age, diagnosed with Chronic otitis media mucosal type with central dry perforation having intact and mobile ossicles, undergoing Type 1 tympanoplasty with and without canaloplasty were included in our study. Patients with sensorineural hearing loss, chronic suppurative otitis media patients having atticofurrow (unsafe) type, ossicular erosion, tuberculosis, granulations, patients having recurrent infection of chronic otitis media were excluded from our study. Patients were divided into 2 groups on alternate basis, group 1 (28 patients) underwent type 1 tympanoplasty and canaloplasty and group 2 underwent type 1 tympanoplasty alone, irrespective of anterior or posterior canal bulge. Pure tone audiometry was done at 3rd and 6th month postoperatively. AC, BC, ABG was assessed at 4 frequencies 500, 1000, 2000 and 4000 Hz. % Closure of ABG average was calculated.

Surgical Technique

The external auditory canal was instilled with 4% lignocaine. The ear and the surrounding areas were painted with 10% povidone iodine solution. The patient was draped with sterile surgical towels. Infiltration was given with 10ml of 2% premix (xylocaine 2%, adrenaline 1:200000) 10ml of normal saline in the post auricular area and external auditory meatus. Canal wash was given with betadine. Using Lempert's endaural speculum, incision was taken at bony cartilaginous 5 mm lateral to fibrous annulus at 6 o'clock and 12 o'clock and joined with horizontal incision.

Posterior meatal skin was elevated laterally up to bony cartilaginous junction. William wilde postaural incision was given 0.5–1 cm away from postauricular groove, temporalis fascia graft of adequate size is harvested. Margins of central perforation were freshened, tympanomeatal flap elevated. Cotton wick was placed over the tympanomeatal flap to prevent bone dust from entering the middle ear (only group 1 patients). Canaloplasty was done for group 1 till fibrous annulus is visualized using appropriate size diamond burrs (especially for reducing ridge) (only group 1 patient). (fig i showing stenosed canal, ii showing canaloplasty procedure, iii showing ossicular status).

Ossicular status was assessed, round window reflux was confirmed. Skeltonising the malleus handle and placement of temporalis fascia graft via underlay technique (type 1 tympanoplasty done for both group 1 and group 2) Anterior tugging was performed. Repositioning of tympanomeatal flap was done. Post auricular wound was closed in layers and mastoid dressing is applied.

Postoperative Follow Up

Patients were put on antibiotics, analgesics, antihistamines for 7 days. Post aural sutures were removed at 10th post op day. Canal pack was removed on 21st post op day. PTA was done on 3rd and 6th month postoperatively.

Statistical Analysis

AC Avg, BC Avg, ABG Avg, closure of ABG avg and % closure of ABG avg were reported as primary outcome measurements, Groups of the study (Group 1 & Group 2) was imparted as primary exposure measure. Count and proportion were done for the qualitative parameters. Checking of normal distribution for continuous variables was done using Shapiro-Wilk test and visual methods such as histograms and Q-Q plots.

Mean values of quantitative measurements comparison was done with the independent sample t-test (2 groups). Results were derived based on assessment in hearing pre

and post operatively was evaluated by degree of closure of ABG when calculated as a percentage. (% degree of closure of ABG avg) Comparison of outcomes with the categories as per the study groups was done by chi square test. p value < 0.05 was indicating significance statistically. Data analysis was done using co-guide software.

Results

Patients were divided into group 1 (type I tympanoplasty with canaloplasty) and group 2 (type I tympanoplasty) on alternate basis. None of the patients had anatomically wide canals. In the study Group 1, 11 (39.29%) participants were male and 17 (60.71%) were female. In Group 2, 9 (32.14%) were male and 19 (67.86%) were female. (table i)

In Group 1, 8 (28.57%) participants age was in between 15 and 30 years, 16 (57.14%) belonged to 31 to 45 years, 4 (14.29%) belonged to 46 to 60 years. In Group 2, 11 (39.29%) had age between 15 and 30 years, 12 (42.86%) belonged to 31 to 45 years, 5 (17.86%) were between 46 and 60 years. (table ii). The diseased ear was right for 24 patients in our study, for 32 patients it was left. (together considering group 1 and group 2). All had central dry perforation with intact and mobile ossicles.

The mean of preop AC avg of group 1 was 50.60 ± 7.67 and group 2 was 51.09 ± 8.47 , the mean difference of preop AC avg between Study Group found was not significant as the p value = 0.8203. The mean of preop BC avg of group 1 was 10.16 ± 2.68 and group 2 was 10.80 ± 2.17 , the mean difference was insignificant since the p value was 0.3269.

The mean of preop ABG avg of group 1 was 40.44 ± 7.37 and Group 2 was 40.29 ± 7.79 . The mean difference of preop ABG avg between study group was statistically not significant with p value of significance being 0.9406.

Median of post op AC avg at 3 months for group 1 was 28.00 (IQR 23.0 to 36.85) and for group 2 it was 33.000 (IQR 30.19 to 36.95), the difference in the post op AC avg at 3 months between study group was reported as significant where p value was 0.0126. Among the people in group 1, median of post op BC avg at 3 months was 10.00 (IQR 8.71 to 11.05) and for group 2 it was 11.000 (IQR 9.38 to 12.0), the difference was statistically not significant where p value was 0.0697. Mean of post op ABG avg at 3 months for group 1 was 19.09 ± 7.68 and group 2 was 33.84 ± 5.78 . The mean difference of post op ABG avg at 3 months was insignificant since p value was 0.0532.

Among the people in group 1, median of post op AC avg at 6 months was 21.50 (IQR 20.0 to 24.5) and for group 2 it was 28.98 (IQR 27.96 to 33.56), the difference between study group was significant (p value < 0.001).

Among the people in group 1, median of post op BC avg at 6 months was 10.00 (IQR 9.75 to 11.0) and for group 2 it was 10.50 (IQR 9.88 to 12.0), the difference was statistically not significant. The mean of post op ABG avg at 6 months for group 1 was 12.95 ± 5.98 and for group 2 it was 20.04 ± 6.52 . The mean difference between the 2 groups was statistically significant with p value being < 0.001 .

The mean closure of ABG avg at 3 months for group 1 was 21.35 ± 9.13 and group 2 was 17.48 ± 9.74 . The mean difference of closure of ABG avg at 3 months was statistically not significant, p value being 0.13. (table iii) The mean closure of ABG avg at 6 months for group 1 was 26.07 ± 10.44 and group 2 was 20.25 ± 7.76 . The mean difference of closure of ABG avg at 6 months between study group was known with statistical significance because the value of p was 0.0215. (table iv)

The mean % closure of ABG avg at 3 months for group 1 was 52.21 ± 18.59 and group 2 was 41.33 ± 19.84 . The mean difference in % closure of ABG avg at 3 months between study group was statistically significant since the p value = 0.0387. (table v) Among the people in group 1, median % closure of ABG avg at 6 months was 72.16 (IQR 58.96 to 74.61) and for group 2 it was 51.15 (IQR 41.34 to 60.03), the difference in the % closure of ABG Avg at 6 months was statistically significant with p value < 0.001 . (table vi)

In group 1, 27 (96.23%) participants had intact graft status at 6 months and for 1 patient (3.57%) the graft got rejected. In group 2, 26 (92.86%) participants had intact graft and 2 participants (7.17%) had rejected graft. The proportion difference of graft status at 6 months in the two study groups showed no significance with 'p-value' of 1.000.

Discussion

Our study included a total of 56 subjects who met the inclusive criteria with 50% (28 subjects) in group 1 undergoing type I tympanoplasty with canaloplasty (T+C) and 50% (28 subjects) in group 2 undergoing type I tympanoplasty without canaloplasty (T alone). Diseased ear was right for 24 patients in our study, for 32 patients it was left. (together considering group 1 and 2). All had central dry perforation with intact and mobile ossicles.

In both the groups, the majority belonged to 30 to 45 years. Since children are poor candidates for tympanoplasty and are likely to suffer from recurrent upper respiratory tract infections, our study excluded patients below 15 years. In Prakash et al.'s study, majority belonged to the 21–30 age group in both the study groups. [4] Kumaraswamy et al. also had a much younger age group in their study, majority being 21–30 age group. Among patients with 15–60 years of age,

average age of T + C group in our study was 27.4 years and it was 26.6 years in the T-alone group [5]. This could be because of newer advancements in science which helps to diagnose the disease at an earlier age and the public awareness raised about the complications linked to chronic otitis media by medical professionals [6, 7].

The mean 3-month post-op ABG average in T + C group was 19.09 ± 7.68 and T-alone group was 22.81 ± 6.32 . The mean difference of 3-month post-op ABG average between study groups was not statistically significant with p value 0.0532. In a study conducted by Prakash et al., the mean 3-month postop ABG in T + C group was 17.57 ± 7.52 and it was 17.20 ± 4.90 in T-alone group [4]. The mean post-operative ABG was 9.9 ± 3.8 dB after 3 month of follow up in the T + C group and it was 12.1 ± 5.2 dB in the T-alone group in Prasad et al.'s study. They found a significant statistical difference in improvement in ABG gap at the third post-op month between the 2 groups ($p = 0.005$) [8].

The mean 6-month post-op ABG avg in T + C group is 12.95 ± 5.98 and in T-alone group is 20.04 ± 6.52 . The mean difference of 6-month post-op ABG avg among the study groups was statistically significant with p value < 0.001 . Postoperatively at six month follow up, average ABG in T + C group was 13.68 dB and in T-alone group it was 17.40 dB in Mallick et al.'s study [9, 10]. According to Morrison et al., canaloplasty is beneficial for patients who have anterior perforations involving more than 25% of the tympanic membrane [11].

In our study, the average gain in ABG closure at 3 months (as compared with preoperative value) in T + C group was 21.35 ± 9.13 and T-alone group was 17.48 ± 9.74 . The mean difference of closure of ABG avg at 3 months among the study groups was statistically not significant with p value 0.1311. Gupta et al. reported postoperative ABG closure in T + C group was $15.76 \text{ dB} \pm 6.75$ and ABG closure in T-alone group was $14.87 \text{ dB} \pm 5.99$ with a p value for the difference in ABG distribution among the two groups being 0.606, at the end of 12 weeks [9]. The ABG closure in Prakash et al.'s study at 3 months in the T + C group was 13.48 ± 2.58 and it was 11.26 ± 2.23 in the T-alone group with the mean difference in ABG closure between two groups being "statistically significant" with a p value < 0.001 [4].

The percentage degree of closure (calculated as a percentage) of the ABG is the most recommended tool for hearing improvement as said by "The American Otolosclerosis Study Group". Click or tap here to enter text. The mean % Closure of ABG avg (compared with preop ABG) at 3 months in T + C group was 52.21 ± 18.59 and T-alone group was 41.33 ± 19.84 . The mean difference of

% Closure of ABG at 3 months in Groups was statistically significant with p value 0.0387.

The average gain in ABG closure at 6 months in T + C group is 26.07 ± 10.44 and in T-alone group was 20.25 ± 7.76 . The mean difference of closure of ABG avg at 6 months in the study groups was statistically significant with p value 0.0215. Mallick et al. reported "air bone gap closure" of 11.4 dB in the group with canaloplasty and 10.36 dB in the group without canaloplasty at post-operative 6 months. Maximum ABG closure, were in the range of 26–75% (moderate air bone gap closure) in both groups [10]. They could achieve moderate improvement in the percentage closure of ABG with approximate difference of 4 dB among the two groups which was statistically significant [10]. In a study conducted by Morrison et al., they found that the perforation closure rate for medial graft tympanoplasty was significantly more (91.6%) if canaloplasty was carried out than if it was not (69%) ($p = 0.02$) [11].

The median % closure of air bone gap average 6 month postoperatively among T + C group was 72.16 and in T-alone group was 51.15. The difference in the % closure of ABG avg at 6 months between the study groups in our study was statistically significant with p value < 0.001 . In T + C group, 96.23% had intact graft status at 6 months and 3.57% had graft rejection. In T-alone group, 92.86% had intact graft status and 7.17% had rejected graft. The difference in the graft status at 6 months between the study group was statistically not significant with p-value 1.000. The results were similar in the study by Gupta et al., postoperatively at 3 months 94.3% of the T + C group showed successful graft uptake, compared to 88.57% of the T-alone group. The difference between the two groups, was not statistically significant, p value being 0.356 [9]. Tympanoplasty with canaloplasty group had a slightly higher success rate of graft uptake than those who underwent tympanoplasty alone, but the p value was not significant, whereas in a study by Morrison et al., it was significant. Similar result was observed in Prakash et al.'s study where the T + C group achieved 98% graft uptake and- T-alone group had 92% uptake [4]. Kumaraswamy et al.'s study reported that at the end of 3rd post-operative month there was 100% graft acceptance rate in T + C group and 96% in the T-alone group [5]. A study found that the T + C technique had a 92% graft success rate and the T-alone procedure had an 84% success rate [10]. Additionally, it was noted that when tympanoplasty and canaloplasty were performed together, graft uptake increased to 91.3% [7]. According to Verma et al., the success rate for myringoplasty alone was 85%, but when canaloplasty was performed in companion, the overall success rates increased to 95% [12].

The current study thus supports the value of tympanoplasty with canaloplasty for improving audiometric threshold. Prasad et al. noticed a significant ABG improvement in patients who had undergone canaloplasty to those who had not and also noticed better visualization and surgical access once canaloplasty was performed [8]. Additionally, Gupta stated that the group who underwent tympanoplasty with canaloplasty had better outcomes in terms of graft uptake and ABG closure compared to tympanoplasty alone group, though the difference was not significant [9]. According to Morrison et al., if exposure is limited because of the anatomy of the bony canal, canaloplasty should be taken into account when using medial graft techniques because it offers benefits regarding closure rate [11]. Combining canaloplasty and tympanoplasty is recommended, as said by Prakash et al., because it helps in proper placement of the graft thereby preventing lateralization. Additionally, it increases graft uptake and hearing improvement [4]. These results support Kumaraswamy et al.'s study that, in patients with conductive deafness, tympanoplasty with canaloplasty offers stronger support for clinical application [5]. Mallick et al. reaffirmed that the time saved in grafting makes up for the time lost in drilling during canaloplasty. In cases of tympanoplasty with canaloplasty, postoperative care is better as problems of stenosed canal become resolved.

Conclusion

The dictum for managing chronic otitis media tubotympanic type is type 1 tympanoplasty which is practiced since antiquity. Though the results are often favourable, but in aberrant anatomy lies the necessity of canaloplasty to get rid of hindrances. Canaloplasty is safe, effective and requires less learning curve in order to practice routinely. It not only renders panorama view of surgical field by removal of bony overhangs but also aids in excellent functional outcome in the form of % closure of ABG. Hence canaloplasty is added as an adjunct to routinely performed aural surgeries to enhance their outcome.

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Declarations

Conflict of interest None.

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