Original Research Article

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Surgical outcome of type I tympanoplasty in different types of mucosal chronic otitis media: a prospective study

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ABSTRACT

Background: Chronic otitis media (COM) is a long-standing infection of middle ear cleft, causes severe destruction and leading to irreversible sequelae. The interval to convert discharging ear into dry is variable. Extensive counselling is required to keep these patients motivated for prolonged treatment duration. Hence, the study was conducted.

Methods: A prospective study was carried out at NKP Salve and Lata Mangeshkar Hospital Nagpur, Maharashtra, between the age group of 16-60 years, who underwent type 1 tympanoplasty. Results were statistically analysed with respect to graft uptake, hearing improvement and size of perforation over a period of 2 years. Temporalis fascia was taken as a graft material.

Results: Out of 70 cases, 38 cases had inactive ears and 32 cases had minimal, mucoid ear discharge (Active ear), which bacteriologically showed no organism. M:F ratio was 1.12:1. Graft uptake was successful in 92.11% of the cases in inactive group and 93.75% of the cases in active group. Graft uptake was 100% in small and moderate perforation. Hearing improvement was achieved in 71.05% of cases in the inactive group and 78.12% of cases in the active group, as measured by closure of the air-bone gap (ABG) and improvement in conductive hearing (significant >10 dB). We found no difference in the success rates.

Conclusions: Presence of minimal discharge will not affect the surgical outcome of type 1 tympanoplasty in terms of graft uptake, hearing improvement and size of perforation.

Keywords: Type 1 tympanoplasty, Inactive ear, Active ear, ABG

INTRODUCTION

Chronic otitis media (COM), an infection of middle ear cavity, which leads to destruction of middle ear along with mastoid and further causes irreversible changes. COM leads to perforation of pars tensa or pars flaccida, most probably as an outcome of previous infection with acute otitis media, due to negative pressure of middle ear cavity or serous otitis media. COM is a serious health issue in society associated with recurrent discharge via a perforated ear drum. The world health organisation estimated that the prevalence rate of acute suppurative

otitis media in India is around 17-20%, chronic suppurative otitis media is 7.8% and of otitis media with effusion is not yet known.³

Classification of COM, based on inflammation of lining mucosa and presence of mucoid discharge in patient as active mucosal type of COM, inactive mucosal type of COM, active squamosal type of COM and inactive squamosal type of COM, healed COM.¹ Spontaneous healing of chronic tympanic membrane perforation is not predicted and medical interventions are not sufficient. Tympanoplasty is indicated for closure of perforation of

mucosal type of COM. The aim of tympanoplasty is to avoid recurrent ear discharge and maintain and restore middle ear function.² In the literature, there are various factors which can affect surgical outcome including age, size of perforation and site, opposite ear status, the graft type and condition of previously operated ear.1 Tympanoplasty can be performed on inactive ear with perforation or moist ear with perforation. Most otologists have a belief that presence of active discharge in ear is not an indication for the surgery (tympanoplasty) because of presence of active infection which can cause graft rejection. In order to prevent failure of graft, course of antibiotics is often preferred and allow the moist ear to become completely free of moisture before surgery. Time span required to convert wet ear into dry is unpredictable and variable and it can lead to multiple hospital visits. In our country, most of the patients are going to hospitals from distant and inaccessible areas, finds it very difficult to go for regular checkup and follow up, even to nearby hospitals, adds to financial expenditure. Along with extensive patient counselling, a high grade of motivation is utmost important to keep all these patients motivated for prolonged duration.4

Hence, we conducted the study to determine the outcome of tympanoplasty type-1 in different types of mucosal COM at our tertiary care hospital.

Aims and objectives

Aims and objectives were to compare the incidence of graft uptake in inactive and active ears, to compare the post operative hearing improvement in inactive and active ear and to compare the hearing improvement according to size of perforation.

METHODS

Study design

A prospective study

Duration of study 2 years after obtaining IEC clearance for the study from Nov 2019- Oct 2021.

Study population

The study included 70 cases between age group of 16 to 60 years of either sex, presented with mucosal type of COM and underwent type 1 tympanoplasty at tertiary care hospital (NKP Salve institute of medical science and research centre and Lata Mangeshkar hospital) during the study period of 24 months. Temporalis fascia was used as graft material in all cases.

Sampling technique

By using a convenient sampling technique, every consecutive patient with Mucosal type COM who visited the ENT OPD and satisfied the inclusion and exclusion

criteria were selected in the study.

Cases were selected according to following criteria.

Inclusion criteria

Patients with age group of 16 to 60 years of either sex. Patients with small, medium, large, subtotal central perforation. Patients with mild to moderate conductive hearing loss. Patients with intact and mobile ossicular chain. Patients with inactive ear for minimum of 6 weeks prior to surgery. Patients with minimal mucoid discharge in the middle ear which on culture and sensitivityshowed no microorganisms. Patients with good general, physical and mental health.

Exclusion criteria

Patients with sensorineural or mixed type of hearing loss. Patients with previous ear surgery. Patients with active upper respiratory tract infection. Patients with coexisting congenital abnormalities like cleft lip, cleft palate, congenital ear deformities. Those patients who failed to keep follow up of 3 months.

Patients who fulfilled the above-mentioned criteria for selection were taken as subjects for the study after taking an informed and written consent. The data of the patient was collected in a case report proforma.

For the study purpose tympanic membrane perforation were classified as:

Small perforation: Occupying less than the size of one quadrant.

Medium perforation: Occupying more than the size of one quadrant but less than two quadrants.

Large perforation: Occupying more than the size of two quadrants but less than three quadrants.

For the purpose of study-Successful graft uptake is a stable, healed, clinically intact tympanic membrane. Graft failure includes residual perforation, reperforation, medialization of graft, and complete graft failure. Hearing improvement after surgery is said to be significant when ABG closure (ABGC) is more than or equal to 10 dB.⁵

In present study, total 70 cases of mucosal type of COM were included. These cases were divided into two groupsinactive and active. "inactive" group included mucosal type of COM with dry ear for a minimum period 6 weeks. Cases with minimal mucoid ear discharge which were bacteriologically negative on culture were included in "active" group. The two groups were analysed for similarity to be comparable. All cases underwent type 1 tympanoplasty. The graft up take rate and hearing improvement was compared between these two groups and post-operative pure tone audiometry was done at the

end of 3 months follow-up and mean ABG closure was calculated by subtracting Mean Postoperative ABG from mean pre-op ABG.

RESULTS

In present study, total 70 cases of mucosal type of COM were included.

Most of the patients in both inactive and active group belonged to the age group between 11-20 (44.29%) years followed by 16 (22.86%) in age group of 41-50 years. Mean age of presentation was 28.78±9.42 years (Figure 1).

In present study out of 70 cases, 37 (52.86%) were males and 33 (47.14%) were females. Male: female ratio was 1.12:1 (Figure 2).

In present study out of 70 cases, maximum number of the cases i.e., 25 (35.71%) cases had small sized central perforation followed by 24 (34.29%) cases with moderate sized central perforation followed by 17 (24.29%) with large central perforation and only 4 cases had subtotal perforation (Figure 3).

In present study out of 70 cases, on distribution of study subjects according to duration of illness. Majority of 33 (47.14%) cases had duration of illness between 1-5 years followed by 18 (25.71%) cases with duration of illness more than 10 years (Figure 4).

In present study, Right ear was found to be commonly affected in 31 cases (44.29%) as compared to Left ear in 27 cases (38.57%) and bilateral disease was found in 12 cases (17.1%) (Figure 5).

In present study out of 70 cases on distribution, according to the side operated. Majority 38 (54.29%) cases underwent for right ear surgery.

On distribution of 70 study subjects according to presence of middle ear granulation and type of mucosal COM. Out of 31 cases of active type only 01 (3.13%) case had granulation in middle ear and none of inactive group had middle ear granulations.

On distribution of 70 study subjects, according to graft uptake and type of Mucosal COM. In inactive type of mucosal COM, 35 cases (92.11%) had graft uptake while 3 (7.89%) had graft failure. While in active type of mucosal COM, 30 cases (93.75%) had graft uptake and 2 (6.25%) had graft failure. The difference was not significant (x^2 =0.07, p=0.79) (Figure 6).

On distribution of 70 study subjects, according to status of graft among graft failure patients in different type of mucosal COM. Out of 3 graft failure cases of inactive group, medialisation of graft was seen in 01 case and residual perforation was seen in 02 cases. While 02

(6.25%) cases of active type of mucosal COM had residual perforation and none had medialisation of graft (Table 1).

On distribution of 70 study subjects, according to the size of perforation and graft status, failure of graft was seen in 3 cases of inactive ear out of which 2 cases had large perforation and 1 case had subtotal perforation. 2 cases of active type of mucosal COM with large central and subtotal perforation respectively had graft failure, 100% graft uptake was seen in small and moderate perforation in both the groups (Table 2).

On distribution of 70 study subjects, according to pre and post operative audiological assessments in dB for inactive type of COM. Pre-operative mean air conduction (AC) threshold was 44.54 dB (±7.66) which was improved to 33.51 dB (±4.54) postoperatively. There was no change in mean BC threshold after surgery. Preoperative air bone gap was 33.87dB (±6.28) which was improved to 23.66 dB (±3.72) postoperatively. Mean ABG closure (hearing improvement) was 10.31dB (±4.23) (Table 3).

On distribution of 70 study subjects, according to pre and post operative audiological assessments in dB for active type of COM. Pre-operative mean AC threshold in active type of COM was 45.86 dB (±6.01), improved to 34.57dB (+4.27) postoperatively.

There were no changes in mean bone conduction (BC) threshold after surgery. Preoperative ABG was 35.49 dB (± 4.74) which was improved to 24.10 dB (± 3.91) postoperatively. Post operative improvement in AC threshold and ABG was found significant (p<0.05). Mean ABG closure (Hearing Improvement) in this group of patients was 11.40 (± 2.47) dB (Table 4).

Present study shows mean values for ABG closure in dB as per the size of perforation and type of mucosal COM. When mean values for ABG closure in dB was compared in different types of perforation in inactive and active ear using unpaired t test.

The difference in ABG Closure was found to be significant in small central perforation (p=0.02) and not significant in rest of the types. Mean ABG closure was maximum in subtotal perforation (14.91±4.6 dB) in inactive mucosal type of COM as compared to other sizes. While it was maximum in large perforation (12.29±1.24 dB) in active group as compared to other sizes.

The present study shows distribution of the study subjects according to hearing improvement. ABG closure of >10 dB was considered as significant hearing improvement for study purpose. Hearing Improvement was seen in 71.03% and 78.12% in inactive and active type of mucosal COM respectively and the difference was not statistically significant (Table 5).

Table 1: Distribution of study subjects according to status of graft among graft failure in different types of mucosal COM, (n=70).

Graft status	Inactive type of Mucosal COM, (n=38)	Active type of Mucosal COM, (n=32)
Mediatisation	01	00
Residual perforation	02	02
Total graft Failure	03	02

Table 2: Distribution of the study subjects according to the size of perforation and graft status in different types of mucosal COM, (n=70).

Size of perforation	Inactive type of mucosal COM, (n=38) Intact Failure		Active type of mucosal COM, (n=32) Intact Failure	
Small central perforation	12	00	13	00
Moderate central	13	00	11	00
Large central perforation	08	02	08	01
Subtotal perforation	02	01	00	01
Total	35	03	30	02

Table 3: Pre-and post-operative audiological assessment in dB for inactive type of the COM, (n=38).

Variables	Pre- operative mean ± SD	Post- operative mean ± SD	T test, p value
AC	44.54±7.66	33.51±4.54	0.0001*
BC	9.63±3.30	9.68±3.25	0.58
ABG	33.87±6.28	23.66±3.72	0.0001*
Mean ABG	C	10.31±4.23dB	

AC-Air conduction, BC-Bone conduction, ABG-Air bone gap. P<0.05-Statistically significant.

Table 4: Pre-and post-operative audiological assessment in dB for the active type of the COM, (n=32).

Variables	Pre- operative mean ± SD	Post- operative mean ± SD	T test p value
AC	45.86±6.01	34.57±4.27	0.0001*
BC	10.11±3.54	10.22 ± 3.75	0.9
ABG	35.49 ± 4.74	24.10±3.91	0.0001*
Mean ABG	C	11.40±2.47dB	

AC-Air conduction, BC-Bone conduction, ABG- Air bone gap. P<0.05-Statistically significant.

Table 5: Distribution of the study subjects according to hearing improvement, (n=70).

Hearing improvement	Inactive ear		Active ear		Chi square p value
	N	%	N	%	
Yes (ABGC>10 dB)	27	71.05	25	78.15	- 0.5
Yes (ABGC<10 dB	11	28.95	07	27.88	
	38	100	32	100	

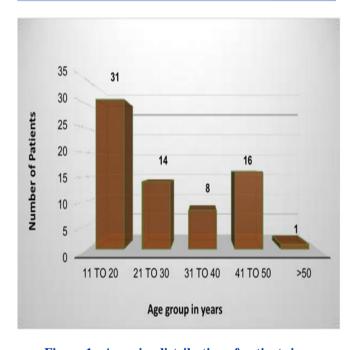


Figure 1: Age wise distribution of patients in different types of mucosal COM, (n=70).

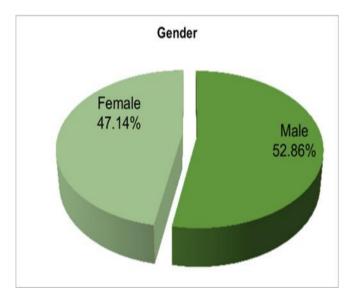


Figure 2: Distribution of study subjects according to gender, (n=70).

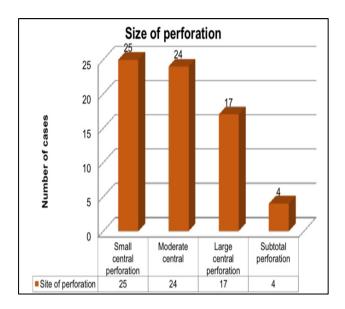


Figure 3: Distribution of study subjects according to the size of perforation, (n=70).

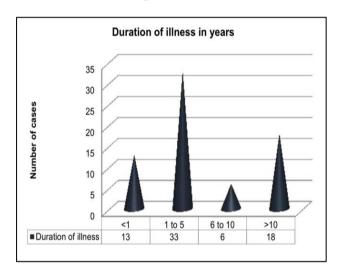


Figure 4: Distribution of study subjects according to duration of illness, (n=70).

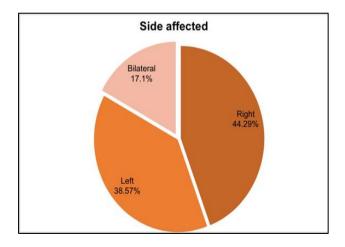


Figure 5: Distribution of study subjects according to the side affected, (n=70).

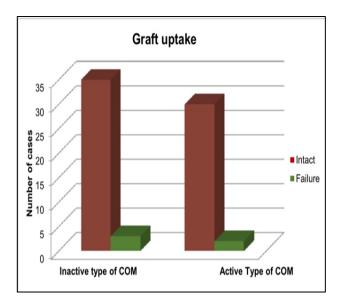


Figure 6: Distribution of study subjects according to graft uptake and type of mucosal COM, (n=70).

DISCUSSION

In study done by Nagle et al, large number of cases seen between age group of 21-30 years.⁶ In other studies carried out by Shankar et al, Gamra et al, Sharma et al, Jaseetha et al and Chakraborty et al had middle age as the most common age group affected, while present study had young age group of 11-20 years.^{4,7-10} Our findings are consistent with the above studies. In present study, majority of 31 (44.29%) cases belonged to 11-20 years followed by 16 (22.86%) cases in 41-50-year age group. Mean age was 28.78±9.42 years. The reason for early clinical presentation can be because of increased awareness regarding healthcare facilities and difficulty in hearing which affects the efficiency at work station, hence seek medical intervention early.

In contrast to the present study, Gamra et al, Chakraborty et al and Mahajan et al studies shown higher mean age as compared to present study finding.^{8,10,11}

In our study, maximum 37 (52.86%) cases were males and rest 33 (47.14%) were females. Male: female ratio was 1.21:1.

Additional research in the same direction done by Gamra et al male:female was 1:2. In contrast to our study, Jaseetha et al, Chakraborty et al and Mahajan et al showed COM, more common in females.⁸⁻¹¹

In our study, majority 33 (47.14%) cases had duration of illness between 1-5 years followed by 18 (25.71%) cases with duration of illness >10 years. Whereas, in Nagle et al, majority of cases had duration of illness <5 years (44%).⁶ While Chakraborty et al had duration of illness <6 months.¹⁰

Right ear was most commonly affected in present study

which was similar to findings by Nagle et al. Because most patients have a dominant right hand, scratching one's ear repeatedly can lead to more right-side involvement. In contrast to our study, Sharma et al, Chakraborty et al and Singh et al found left side ear, most commonly involved. 4,6,10,12

In present study, majority 38 (54.29%) cases had inactive type of mucosal COM and rest 32 (45.71%) cases had active mucosal type of COM. This was comparable with similar studies like Gamra et al and Mahajan et al which showed similar results. 8,11 While Nagle et al and Shankar et al had included equal number of cases of inactive and active type of mucosal COM as they were comparison studies Contrast findings were seen in studies like Sharma et al and Huang et al having a greater number of Active COM cases. 4,6,7,13

In present study, majority 25 (35.71%) cases had small central perforation followed by 24 (34.29%) cases with moderate central perforation followed by 17 (24.29%) cases with large central perforation. Present study showed small central perforation as most common type. Contrast findings were seen in Nagle et al and Mohan et al showed moderate central perforation being most common.^{6,14} While Dhar et al shows subtotal perforation as most common perforation.¹⁵

In our study, out of 32 cases of active COM, only 01 (3.13%) case had granulation in ME while none had so in inactive ear.

Nagle et al found that, out of all cases of active COM (n=50), 12 cases had minimal granulation tissue while 2 developed granulation tissue in inactive middle ear (n=50) which is higher than present study.⁶ While Da Costa et al discussed granulation tissue (96%) as a most prominent pathological feature in COM.¹⁶

In our study, successful graft uptake was 92.11% and 93.75% in inactive and active type of mucosal COM respectively. Failure of graft uptake was seen in 3 cases of inactive COM (n=38) out of which 2 case each had large central perforation, 1 case had subtotal perforation. There were 2 cases of active COM (n=32) with failure of graft, out of which 1 case each had large and subtotal perforation.

Similar studies like Nagle et al, Shankar et al, Gamra et al and Sharma et al showed more graft success in inactive ear as compared to active ear while studies like Mohan et al and Mahajan et al showed overall graft success >90%, 80% and 96 respectively. 4.6-8,11,14 More graft uptake in active type of COM can be due to presence of all the layers of epithelium, inflammatory cells, abundant blood supply, fibrous layer.

In our study, improvement in hearing was seen in 27 cases (71.05%) and 25 cases (78.12%) of inactive COM and active COM respectively. When hearing

improvement was compared in both using chi square test, it was not found to be statistically significant. (p=0.5). In our study, hearing improvement is considered to be significant when ABG closure (ABGC) was more than or equal to 10 dB.

In inactive type of COM preoperative ABG was 33.87 dB (± 6.28) which was improved to 23.66 dB (± 3.72) postoperatively. Mean ABGC (Hearing improvement) in this group of patients was 10.31 dB (± 4.23) dB.

In active type of COM, preoperative ABG was 35.49dB (± 4.74) which was improved 24.10 dB (± 3.91) postoperatively. This was found, significant (p<0.05). Mean ABG closure in this group of patients was 11.40 (± 2.47) dB.

In Ceylan et al study where Hearing improvement was seen in 77.7% cases in inactive ears and 78.4% in discharging ears.¹⁷

The hearing gain among the patients after statistical analysis, is similar to present study findings. Similar results were seen in study by Mohan et al.¹⁴

Thus, the success rate of tympanoplasty in terms of graft take up rate and hearing improvement, as found in present study, was consistent with results of most studies in the literature as shown in Figure 6 and Table 3-5.

As this is a teaching institute the operations were performed by multiple surgeons, and the experience of surgeons may have had an effect on the operative results could be the limitation of the study.

CONCLUSION

Graft uptake was successful in 92.11 percent and 93.75% of the cases in the inactive group and in the active group respectively. In the inactive group, 71.05% of cases had significant improvement in their hearing postoperatively, while in the active group 78.12% had improvement hearing.

According to statistical analysis, there were no significant differences in success rates in active and inactive ears in the current study, in terms of graft uptake rate and hearing improvement. And the effect of size of perforation on outcome, was found to be significant in small central perforation (p=0.02) and not significant in rest of the types. So, we believe that the presence of minimal discharge, which revealed no organism on culture, will not affect the successful outcome of type 1 tympanoplasty procedure.

Clinically, the inactive type of mucosal COM group performed better than the active type of mucosal COM group, but the difference between the two groups was not significant. This may be because of smaller sample size; hence further study is required with larger sample size to evaluate in detail.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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