

Original Research Article

Impact of otorrhoea and ossicular status on the effect of tympanoplasty

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ABSTRACT

Background: The objective of the study was to assess the effect of otorrhoea, ossicular and middle ear status on anatomical and functional results in patients undergoing tympanoplasty with or without mastoidectomy for chronic otitis media mucosal disease.

Methods: This was a prospective study conducted on 100 patients with otological complaints (otorrhoea, hearing loss) attending the out-patient Department of ENT, at Mamata Medical College and Research Hospital, Khammam Telangana state during the period from December 2015 to July 2017. All the patients underwent a detailed general physical, otoneurological evaluation, hearing assessment by pure-tone audiometry prior to surgery. As per MERI the patients were evaluated for factors preoperatively and intraoperatively. Postoperatively the patients were followed up at 3 and 6 months to ascertain the structural (graft take up) and functional (hearing improvement) success.

Results: Otorrhoea was the most common complaint observed (48%). As per Belluci's classification of otorrhoea, maximum number of patients (52%) had a dry ear, wet ears (48%) and persistently wet ears (8%). According to Austin-Kartush classification 50 patients had an intact ossicular chain, defects of the incus in 36 patients, defects in both malleus and incus, stapes and incus was seen in 7 patients each. Majority of the patients 79% had normal middle ear status while 21% of them had middle ear effusion present. Majority of the patients belonged to the group of mild risk MERI (1-3) (n=69) patients, moderate risk category MERI (4-6) (n=26) severe risk (7-12) (n=5). Graft uptake was successful in 78 patients and failure in 22 patients. Hearing Improvement was noticed in 78 patients.

Conclusions: Otorrhoea and middle ear cleft status have an impact on the success of the tympanoplasty, while ossicular status did not have a significant effect on the outcome.

Keywords: Otorrhoea, Ossicular status, Tympanoplasty

INTRODUCTION

Chronic suppurative otitis media is a very common otorhinolaryngeal problem worldwide, especially in developing countries. Around 7.8% of the Indians suffer from this infection according to WHO report, 2004.¹ It is more common in rural areas than urban areas and is associated with poor hygiene, illiteracy and is common among the middle and low income groups.² It is the chronic inflammation of the middle ear cleft which presents with recurrent otorrhoea through a tympanic membrane perforation. Long standing disease can also cause hearing impairment.³

The management of COM is mainly based on two principles, eradication of infection and the closure of the tympanic membrane perforation. This is achieved surgically by tympanoplasty with or without mastoidectomy.⁴ In spite of the availability of a wide range of antibiotics, advanced surgical techniques and newly developed prosthetic materials were unable to reach 100% successful outcomes in tympanoplasty in terms of graft uptake and hearing benefit. This is due to the extent of pathology in the middle. All the associated factors of COM are summarised and assigned a numerical value, the middle ear risk index (MERI), which helps us

to identify the extent of disease and thereby predict the outcome of surgery.

The factors evaluated in MERI include otorrhea, perforation of the eardrum, cholesteatoma, ossicular status, middle ear granulations or effusions, previous surgery and smoking. The success and failure of surgical correction and the factors affecting it are an important part of counselling a patient undergoing surgery.⁵

The present study was undertaken to study the effect of otorrhea, ossicular and middle ear status on anatomical and functional results in patients undergoing tympanoplasty with or without mastoidectomy for chronic otitis media mucosal disease.

METHODS

This was a prospective interventional study conducted on 100 patients with otological complaints (otorrhea, hearing loss) attending the out-patient Department of ENT, at Mamata Medical College and Research Hospital, Khammam, Telangana state during the period from December 2015 to July 2017.

Selection criteria

Inclusion criteria were patient's of age above 10 years, those willing for surgery and diagnosed with COM mucosal disease. Exclusion criteria were patients who were unwilling for surgery, medically unfit for surgery, cases with squamous disease, revision tympanoplasty cases and complicated otitis media.

Study procedure

All subjects fulfilling the inclusion criteria were taken into consideration. In history, importance was given to conditions such as hearing loss, otorrhea, previous otology procedures, tinnitus, otalgia, vertigo and facial paralysis. General physical examinations, ear examinations with otoscope and tuning fork tests with 256, 512, and 1024 Hz were done. Pure tone Audiometry test was performed by a certified trained Audiologist within 1 week before surgery, 3rd month after surgery and 6th month after surgery. It was tested in a sound treated room. Hugson and Westlake technique was used for audiometric evaluation. Test was performed through air conduction and bone conduction. Air conduction included frequencies at 250 Hz, 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz and 8000 Hz. Four frequencies pure tone average was calculated from 500 Hz, 1000 Hz, 2000 Hz and 3000 Hz. It was documented both pre- and post-operatively. The findings were noted in the predesigned audio logical evaluation sheet.

Pre-operatively patency and mucociliary clearance of the Eustachian tube were assessed by instillation of antibiotic ear drops through the tympanic membrane perforation. The perception of taste by the patient was perceived as a

positive response with normal patency of the Eustachian tube. Patients were admitted or called on OPD basis according to the availability of bed in the ward. Oral antibiotic were prescribed the day before surgery and continued for 10 days postoperatively. Part preparation was done on day before surgery. All cases were done under general anaesthesia.

Patients were admitted 2 days prior to surgery, detailed history and clinical examination of ear, nose and throat was done as per the attached proforma. Written/informed consent was taken. All the cases were done under general anaesthesia. Based on pre-operative and intra-operative findings, the middle ear risk index was calculated for each patient and they were stratified into three categories of mild, moderate and severe categories. All patients with discharging ears or unhealthy middle ear status underwent cortical mastoidectomy. On diagnosis of the case of COM mucosal disease, these patients were counselled for surgery. Patients undergoing surgical correction by tympanoplasty with or without mastoidectomy will be assessed pre and intraoperatively by MERI scoring in order to classify and identify the disease category (Table 1).

Table 1: MERI scoring system.

| | | |
|--------------------------------|-------------------------------------|---|
| Otorrhea | Dry | 0 |
| | Occasionally wet | 1 |
| | Persistently wet | 2 |
| | Wet, cleft palate | 3 |
| Perforation of ear drum | None | 0 |
| | Present | 1 |
| Cholesteatoma | None | 0 |
| | Present | 2 |
| Ossicular chain status | Malleus, incus and stapes present | 0 |
| | Defect of incus | 1 |
| | Defect of incus and stapes | 2 |
| | Defect of incus and malleus | 3 |
| | Defect of malleus, incus and stapes | 4 |
| | Ossicular head fixation | 2 |
| | Stapes fixation | 3 |

Postoperatively the patients were followed up at 3 and 6 months to ascertain the structural (graft take up) and functional (hearing improvement) success.

Statistical analysis

Data was entered into Microsoft excel data sheet and was analyzed using SPSS 22 version software. Categorical data was represented in the form of Frequencies and proportions. Chi-square was used as test of significance. Continuous data was represented as mean and SD. Independent t and Man Whitney test were used as test of significance to identify the mean difference between two groups, $p < 0.05$ was considered as statistically significant.

RESULTS

A total of 100 patients who underwent cortical mastoidectomy were included in the study. Sociodemographic and clinical characteristics of the patient were given in Table 2.

Table 2: Socio-demographic and clinical characteristics of the study participants.

| Characteristics | Frequency (N=100) |
|------------------------------|-------------------|
| Age (years) | |
| <20 | 7 |
| 21-30 | 46 |
| 31-40 | 37 |
| >40 | 10 |
| Sex | |
| Males | 48 |
| Females | 52 |
| Clinical symptoms | |
| Otorrhoea | 48 |
| Hearing impairment | 36 |
| Tinnitus | 8 |
| Pain in the ear | 6 |
| Itching in the ear | 2 |
| TM perf side | |
| Right | 33 |
| Left | 57 |
| Bilateral | 10 |
| TMP size and site | |
| Medium Size AI&PI | 2 |
| Large central | 55 |
| Small central AI | 7 |
| Medium size AI&AS | 1 |
| Medium central AI&PI | 11 |
| Small central PI | 6 |
| Medium central AS&A1 | 17 |
| Small central AS | 1 |
| Organisms isolated | |
| <i>Pseudomonas</i> | 28 |
| <i>Proteus</i> | 23 |
| <i>E. coli</i> | 14 |
| <i>Staphylococcus aureus</i> | 6 |
| <i>Enterococcus</i> | 5 |
| <i>Enterobacter</i> | 4 |
| No growth | 20 |
| Smoking status | |
| Yes | 20 |
| No | 80 |
| MERI score | |
| Normal | 0 |
| Mild | 69 |
| Moderate | 26 |
| Severe | 5 |

Maximum number of patients were in the age group of 21-30 years (46%) followed by 31-40 years (37%) and

10% above 40 years and the least among those less than 20 years (7%). Majority of the patients were females (52%) and males were 48%. The male:female ratio being 0.92:1. Amongst the presenting complaints, otorrhoea was the most common followed by hearing impairment, tinnitus, pain in the ear and itching in the ear being the least common complaint. 33% had right sided disease, 57% had left sided disease and 10% had bilateral disease. Left sided pathology was more common in our study group. All patients in the study have tympanic membrane perforations of different sizes affecting various compartments of the pars tensa. Of the total no of patients, 20 of them were smokers and 80 of them were non-smokers. Among the smokers, only 7 (35%) of them had a graft rejection, 13 of them (65%) had a successful surgery. Based on MERI scoring all the patients (100%) were diagnosed as chronic otitis media mucosal type. Majority of the patients belonged to the group of Mild risk MERI(1-3) which was 69 patients, 26 patients came under the Moderate risk category MERI(4-6) and 5% patients had Severe risk (7-12). Aural swab was done for culture sensitivity of the organisms in all patients. The most common organism isolated in aural swab culture was *Pseudomonas* (26%). The other organisms were *Proteus*, *Escherichia coli*, *Staphylococcus aureus*, *Enterococcus*, *Enterobacter* and *Acinetobacter*. No growth was obtained in 20 patients.

According to Bellucci's classification of otorrhoea, patients were classified as dry ear, occasionally wet persistently wet and lastly persistently wet with cleft palate. Maximum number of patients (52%) had a dry ear, 48% had occasionally wet ears and 8% had persistently wet ears. None of the patients presented with a persistently wet ear with cleft palate (Table 3).

Table 3: Bellucci's classification of otorrhoea.

| Category of otorrhoea | Frequency (N=100) |
|---|-------------------|
| Dry | 52 |
| Occasionally wet | 40 |
| Persistently wet | 8 |
| Persistently wet with cleft palate | 0 |

Table 4: Distribution of patients according to ossicular and middle ear status.

| | Frequency (N=100) |
|--------------------------|-------------------|
| Ossicular status | |
| Intact ossicular chain | 50 |
| Incus alone | 36 |
| Malleus and incus | 7 |
| Middle ear status | |
| Normal | 79 |
| Middle ear effusion | 21 |

Austin-Kartush classification was used for evaluating middle ear ossicular status. 50 patients had an intact ossicular chain. Defects of the incus alone were seen in

36 patients. Defects in both malleus and incus was seen in 7 patients and stapes and incus was noted in 7 patients. Majority of the patients (79%) had normal middle ear status while 21% of them had middle ear effusion present (Table 4).

After surgery, the graft uptake was successful in 78 patients (78%) and there was a failure in 22 of them which was further divided into graft failure which was seen in 16 patients and reperforation in 6 patients. Hearing improvement in our study group was assessed based on Belfast rule of thumb which states that postoperative hearing benefit is significant if (operated ear hearing brought to 30 dB or better or to within 15 dB of contralateral ear). Based on this the number of patients who had hearing benefit was 78 (Table 5).

Table 5: Distribution of subjects according to Graft uptake and hearing improvement.

| | Frequency (N=100) |
|---------------------|----------------------|
| Graft uptake | |
| Success | 78 |
| Graft failure | 22 |
| Belfast rule | |
| Success | 78 |
| Failure | 22 |

Comparison of otorrhoea with graft uptake status was given in Table 6. Otorrhoea proved to be a significant factor in the success of surgery as dry ears had a better graft uptake compared to wet ears. P value less than 0.05 at 5% level of significance shows there is significant relationship between otorrhoea and graft uptake.

Table 6: Comparison of ossicular, middle ear status with graft uptake.

| | Success | | Total | X ² | P value |
|--------------------------------|---------|----|-------|----------------|------------|
| | Yes | No | | | |
| Ossicular chain status | | | | | |
| Malleus, incus, stapes present | 10 | 40 | 50 | 2.135 | 0.545 (NS) |
| Defect of incus | 8 | 28 | 36 | | |
| Defect of incus and stapes | 1 | 6 | 7 | | |
| Defect of incus and malleus | 3 | 4 | 7 | | |
| Total | 22 | 78 | 100 | | |
| Middle ear condition | | | | 14.298 | 0.000 (HS) |
| Effusion /unhealthy middle ear | 68 | 11 | 79 | | |
| Yes | 10 | 11 | 21 | | |
| Total | 78 | 22 | 100 | | |

HS- Highly significant, NS- Not significant.

Table 8: Graft uptake and MERI score.

| Graft uptake | MERI score | | | Total | X ² | P value |
|--------------|------------|----------|--------|-------|----------------|------------|
| | Mild | Moderate | Severe | | | |
| Success | 60 | 17 | 1 | 78 | 15.439 | 0.000 (HS) |
| Failure | 9 | 9 | 4 | 22 | | |
| Total | 69 | 26 | 5 | 100 | | |

HS- Highly significant.

Table 6: Otorrhoea and success.

| Otorrhoea | Success | Z | P value |
|-----------|---------|--------|------------|
| Dry | 44 | -8.775 | 0.000 (HS) |
| Wet | 34 | | |
| Total | 78 | | |

HS: Highly significant.

Ossicular status in our study does not have a significant (p value more than 0.05) role to play in the successful outcome of surgery. Nevertheless adequate assessment of the ossicular status is important to plan the surgery and to give adequate hearing benefit for the patient post-operatively. The status of the middle ear was considered as an important factor to decide the outcome of surgery. Adequate clearance of the middle ear disease is important to have a disease free post-operative status which in turn helps in adequate graft uptake. Pre-operative assessment of the Eustachian tube patency is an important factor in assessing the middle ear cleft status which in turn predicts the outcome of surgery. Of the total of 100 patients, 21 of them had non patent Eustachian tube with middle ear effusion of which 11 of them had graft failure, whereas in case of patent Eustachian tube and normal middle ear cleft the success rate was higher (68 out of the 79 were successful).

Patients with a lower MERI score had successful outcome of surgery whereas those with a higher score had lesser chances of successful surgery. Out of 100, 60 patients belonging to the mild MERI and 17 from the moderate risk group had a successful surgery whereas only 1 patient out of the severe category had a successful surgery (Table 8).

DISCUSSION

Chronic otitis media (COM) is an inflammatory condition of the middle ear cleft associated with persistent tympanic membrane perforations and otorrhea and can lead to thickening of middle ear mucosa and mucosal polyps. It may be classified COM squamous and COM mucosal.⁵ COM when left untreated can lead to various morbidities and in certain cases may cause serious temporal and intracranial complications.⁶

The MERI was presented by Becvarovski and Kartush and it generated as a numeric indicator of the severity of middle ear disease, to stratify the cases in different prognostic categories. MERI score includes factors which influence the outcome of surgery.⁷ In this study, we are evaluating the efficacy of the MERI score in predicting the outcome of surgery and also the effect of otorrhea, ossicular status and middle ear status on the successful outcome of tympanoplasty with or without mastoidectomy.

In the present study, the most common age group affected with COM was 21-30 years (46%), followed by 31-40 (36%) and least in the age group of less than 20 years. This was similar to the studies of Kumar et al.⁵ According to Glasscock, though otitis media is a disease which occurs commonly in paediatric age group, the mean age at which the disease manifests is 20-29 years. Due to this reason, it is more commonly seen in young adults.⁸

Feroze et al in his study found a female predominance, out of 113 patients, 69 were female (61%) and 49 were males (39%). This was in accordance with our study which shows a female predominance with 52% females and 48% males.⁹

In our study, maximum number of patients (52%) had a dry ear, 48% had occasionally wet ears and 8% had persistently wet ears. While 62 of them had more than three months discharge free period before the surgery, 35 of them had less than three months, 3 of them had active discharge at the time of surgery. In patients with discharge free period of more than three months, 100% graft uptake was seen. Of the 52 patients who had a dry ear, 44 of them had a successful graft uptake (84.6% success), whereas in the 48 wet ears, 34 had a successful graft uptake (70.8% success). Therefore it is preferable to make the ear dry preoperatively in order to achieve the best results. These findings were comparable to the studies of Pinar et al and Sarker et al.^{10,11}

The success of hearing reconstruction of the hearing mechanism depends on the pre-operative ossicular status. An intact ossicular system with only a perforation in the tympanic membrane gives the best results. The most common ossicle to be eroded is the long process of incus due to the nature of blood supply to the incudostapedial joint. In our study, there is erosion of incus in 36 patients. There was erosion of incus and stapes and incus and

malleus in 7% each. An intact ossicular chain was seen in 50 patients (50%). This was in accordance with the observations of Mohammadi et al and Ahmed et al.^{12,13} However, several studies state that the presence of malleus handle is an important factor which affects the outcome. Hence defect of malleus is given a higher MERI score than defect of incus or stapes. The studies conducted by Wilson et al show that the presence of handle of malleus preoperatively gives a better postoperative hearing outcome. They said that the presence of an intact stapes did not affect initial hearing outcome. However, patients with an intact stapes had better long term hearing outcomes than those with erosion of stapes. Ossicular fixation is less common in CSOM compared to ossicular necrosis.¹⁴ In our study, there was no case of ossicular fixation, and there was no significant relationship between the ossicular status and outcome of surgery.

The status of the middle ear mucosa also affects the rate of postoperative graft success. In our study, 21 patients had unhealthy middle ear mucosa with effusion noted in the tympanic cavity. 11 out of these patients had an unsuccessful surgery which can be attributed to the presence of middle ear infection and inadequate removal of this during surgery. This was correlated with the finding of a non-patent Eustachian tube in these patients. In a study by Yurrafl et al, the rate of graft success was 93.5% in patients with normal middle ear mucosa, whereas it was 75% in tympanosclerotic ears and 44.4% in patients with granulation tissue in the middle ear.¹⁵

Controversy exists in the results of tympanic membrane closure rate and hearing improvement in smoker and nonsmoker patients. In a study of 132 patients, performed by Cantrell, success rate in nonsmokers was 92.5% and 43.7% in smokers.¹⁶ In our study, smoking was not seen as an effect on tympanic membrane closure rate and hearing improvement; however, we did not follow patients for a long time.

Hearing benefit was assessed by various methods. According to Belfast rule of thumb, postoperative hearing benefit is significant if air conduction threshold in speech frequency range is equivalent to 30 dB or if inter aural difference is equal to 15 dB. In some studies, only the air conduction threshold is taken into account. In our study, we have measured the average air- bone gap closure at speech frequencies (500 Hz, 1 kHz, 2 kHz and 3 kHz) based on the guidelines given by the committee on hearing and equilibrium, American academy of otolaryngology head and neck surgery. In our study found that 78% patients had a successful graft uptake and 21% had a failure. This was similar to the studies of Kalyanasundharam et al.¹⁷ He noted that the overall success rate of tympanoplasty is 74% according to graft status. In another study by Gersdoff et al the success rate in hearing outcomes was 75.6% and observed that the factors influencing the hearing improvement were

presence of middle ear alterations and surgeon experience.¹⁸

In our study, 60 patients belonging to the mild MERI and 17 from the moderate risk group had a successful surgery whereas only 1 patient out of the severe category had a successful surgery. This is comparable with various studies.¹⁸

CONCLUSION

The findings of the study concluded that otorrhoea and status of the middle ear cleft have an impact on the success of the surgery, while ossicular status did not have a significant effect on the outcome. MERI scoring was considered to be very important scoring system which helps in assessing and analyzing the patient pre-operatively and intra operatively that helps in predicting the outcome of surgery.

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