

ORIGINAL RESEARCH

To Assess Hearing Outcome following Tympanostomy Tube Insertion in Otitis Media with Effusion

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ABSTRACT

Background: Otitis Media with Effusion (OME) is the effusion in middle ear and is commonly seen in children. It causes conductive hearing loss and increased risk of acute middle ear infections. It is mostly a paediatric problem, and leads to poor scholastic performance. It may be managed medically or surgically and surgical management includes grommet insertion or concurrent adenoidectomy with grommet insertion. Our study evaluates the use of ventilation tubes in management of OME. To study the symptomatology of otitis media with effusion (OME), to assess hearing following tympanostomy tube insertion and to determine the complications of tube insertion procedure.

Materials and Methods: This was prospective study done at Jawaharlal Nehru Medical College and Hospital, Bhagalpur from July 2021 to March 2022. Fifty patients of otitis media with effusion were studied and underwent Grommet/ventilation tube insertion and they were followed up or 1, 3 and 6 month interval to determine the improvement in hearing ability.

Results: Patient age ranged from 6 years to 50 years and the male to female ratio was 1.17:1. Both the ears were found to be equally involved. A total of 27 (54%) cases had average of 11 to 20 dB hearing loss by PTA. Most common type of impedance was B type seen in 40 (80%) cases. The overall complication rate in our study was 9 cases, ie 18%. Pure tone audiometry (PTA) is important to evaluate hearing outcome and these readings gradually improved post operatively corresponding to improvement in the hearing capacity of the affected subjects.

Conclusion: Otitis media with effusion (OME) has varied clinical presentation; it is more common in children and adolescents without any gender preponderance. Tympanostomy tube insertion is one of the ideal treatment choices for Otitis Media with effusion with significant improvement in post-operative PTA readings which can lead to a better quality of life.

Key Words: Otitis media with effusion, Tympanostomy tube insertion, Pure tone audiometry.

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INTRODUCTION

Otitis Media with Effusion (OME) is the effusion in middle ear without any evidence of infection and is commonly seen in children. The prevalence in adults is 0.6% while it is 20%

in 2 years old.^[1] OME can lead to conductive hearing loss and increased risk of acute middle ear infections. As it is mostly a childhood problem, evaluation can be difficult and also leads to poor scholastic performance. Management of OME may be without intervention, medical management and surgical management. Medical therapies include oral/nasal steroids, oral/intranasal antihistaminic drugs, mucolytic agents, nasal decongestants and auto ventilation.^[2] Surgical management include grommet insertion or concurrent adenoidectomy with grommet insertion.^[3] Our study evaluates the use of ventilation tubes in management of OME with an intention to supplement the controversial data in management of OME.

AIM OF THE STUDY

To study the symptomatology of otitis media with effusion (OME), to assess hearing following tympanostomy tube insertion and to determine the complications of tube insertion procedure

MATERIALS & METHODS

This was a prospective study conducted in department of ENT at Jawaharlal Nehru Medical College and Hospital, Bhagalpur from July 2021 to March 2022.

Institute Ethics committee approval was obtained before the start of study. Written informed consent was taken from all patients and from parents/ guardians in case of minors.

Patients aged between 6 years to 50 years in whom chronic middle ear effusion was diagnosed based upon detailed clinical history, clinical evaluation, otoscopy, examination under microscope, pure tone audiometry and tympanometry formed the study population.

Inclusion Criteria:

Subjects aged between 6 years to 50 years of either gender having otitis media with effusion.

Exclusion Criteria:

- Patients below 6 years and above 50 years of age
- Patients with previously operated ear.
- Patients having perforation of tympanic membrane and disease of pars flaccida were excluded
- Cases with severe sensorineural deafness
- Patients of diabetes mellitus, hypertension, tuberculosis and other chronic diseases were excluded
- Patients presenting with post nasal mass were also excluded

Method of Study:

Subjects aged between 6 to 50 years of age with unilateral or bilateral otitis media with middle ear effusion were included; these also included patients who had courses of analgesics/antibiotics for episodes of acute infection. The clinical diagnosis was established using otoscopy, pneumatic otoscopy, otomicroscopy, pure tone audiometry and tympanometry. All identified subjects who fulfilled the inclusion criteria outlined were included in the study. Clinical diagnosis using clinical history of the patient, tuning fork tests, otoscopic examination of ear, followed by visualisation of tympanic membrane using otomicroscopy and pneumatic otoscopy was done. Diagnosed cases were first managed by medical treatment, the patients were followed up for 21 days and those not responding to medical management were taken up for ventilation tube insertion. Patients were followed up at 1, 3 and 6 month intervals.

Pure Tone audiometry and Impedance audiometry:

Hearing thresholds was measured using pure tone audiometry test showing the level of hearing loss. Impedance audiometry was used to assess the status and mobility of tympanic membrane and middle ear cavity along with acoustic reflex pathway. Impedance audiometry is also called as tympanometry, acoustic immittance test. Middle ear effusion is easily diagnosed using Tympanometry. Ventilation tube was inserted subsequently.

After pre-operative assessment and confirmation of diagnosis, grommets were inserted under general anesthesia for small children and under local anesthesia for those older. The tube insertion was short term insertion unlike the long term ventilation tube insertion which remains in place for up to 3 years.

Local anaesthesia was employed with adults. Topical anaesthetic spray (e.g. xylocaine) was applied to the tympanic membrane 10 minutes before the procedure. Alternatively the deep ear canal was injected with local anaesthesia with an infiltration needle. A ear speculum was introduced into the ear canal, under an operating microscope. A radial incision was made in the anteroinferior quadrant around the region of the light reflex with a myringotomy knife. Incisions in the posterosuperior quadrant were avoided as they could injure the ossicular chain or the chorda tympani. The incision was made large enough to accommodate a ventilation tube. The middle ear effusion was aspirated with a microsuction tube before inserting the grommet. A ventilation tube was picked up with crocodile forceps and introduced into the ear canal. The tube was placed on the tympanic membrane adjacent to the myringotomy opening. Adequate postoperative care was given and patients were followed upsubgroups.

RESULTS

This was a prospective study in which a total of 50 ears were studied in patients diagnosed with otitis media with effusion. There were 27(54%) males and 23(46%) females and the male to female ratio was 1.17:1. Mean age of male patient's was 17.43 years and of females was 15 years.

Table 1: Mean age and age distribution of the patients

	Age in years (+/- STDEV)	
Total patients	15.9 ± 9.9	
Females	15.17 ± 9.95	
Males	17.43 ± 10.29	
P value	0.503483	
Age distribution (in years)	No of cases	Percentage (%)
6-14	29	58%
15-24	12	24%
25-34	7	14%
35-44	0	0%
45-50	2	4%

The mean age (mean±S.D) of the patient was 15.9±9.9 years with range 6 to 50 years. There was no statistically significant difference between mean age of males and females (>0.05). The proportion of the patients in the age group 6-14 years (58%) was significantly higher than other age group. The mean age of male patients in our study was 17.43 years which is higher than that of females 15.17 years. Most number of patients was in the age group 6-14 years followed by 15 to 24 years showing that the incidence of OME decreased with age.

Laterality of ear involvement: Right ear was affected in 25(50%) cases and left ear was affected in 25 (50%) cases, ie, both the ears were found to be equally involved in our study.

Table 2: Chief complaints at time of presentation

Presenting complaint	No of patients *	Percentage (%)
Aural fullness	32	64%
Ear pain	39	78%
Hearing impaired	38	76%
Tinnitus	14	28%
Nasal block	23	46%
Running nose	27	54%

* More than one complaint was present in given number of patients

The most common presenting complaint was ear pain (78%) followed by impairment in hearing (76%). Tinnitus was seen in 28% of the patients presenting with OME. No patient had past history of any chronic disease, surgical procedure and trauma.

Otoscopic features prior to ventilation tube insertion: The most common otoscopic findings in OME was dull lusterless amber colored tympanic membrane seen in 28 (56%) patients followed by retracted tympanic membrane and handle of malleus foreshortened in 14 (28%) cases, presence of air bubbles in 6 (12%) cases and presence of fluid level in 2 (4%) cases.

Pre-operative Audiological tests- Pure Tone Audiometry (PTA): A total of 27 (54%) cases had average of 11 to 20 dB hearing loss, 11 (22%) cases each had hearing loss of 0-10dB and 21-30dB and 1 (2%) had hearing loss of 31-40 dB.

Type of Impedance Pre-operative: In our study the most common type of impedance was B type seen in 40 (80%) cases followed by C Type observed in 10 (20%) cases.

Table 3: Pure Tone Audiometry (PTA) reading Comparison Pre-operative value and subsequent follow up at 1 month, 3 months and 6 months

Pre-op reading	25.9294 \pm 5.86
1 month follow up	20.9346 \pm 5.3
3 month follow up	18.5402 \pm 5.57
6 month follow up	16.9568 \pm 5.924
P value Pre-op vs 1 month f/u	0.0000226577
P value Pre-op vs 3 month f/u	0.000040688
P value Pre-op vs 6 month f/u	0.00000168
P value 1 month vs 3 month f/u	0.0306
P value 1 month vs 6 month f/u	0.0006471
P value 3 month vs 6 month	0.172

All PTA readings in our study were significant when compared between pre-operative values and subsequent follow ups. Comparison between P value at 3 month and at 6 month visit was, however, non-significant.

Table 4: Extrusion of Grommets/Ventilation Tube: At the end of 1, 3 and 6 months

Extrusion of Grommet/Ventilation tube	N (Cumulative Number)
1 month	5
3 month	17 (12+5)
6 month	47 (30+17)
No extrusion at 6 month follow up	3

Most of the Grommets/Ventilation tube were excluded at 6 months (N=47)

Complications observed in the study population: The most common complication was myringosclerosis that was observed in 5(10%) cases, followed by tympanic membrane atelectasis seen in 3 (6%) cases and permanent perforation seen in 1 (2%) case. The overall complication rate in our study was 9 cases, ie 18%.

DISCUSSION

This study was conducted with the aim of assessing hearing outcome in otitis media with effusion following tympanostomy tube insertion. The study population chosen was scrutinized with proper implementation of inclusion criteria, the results obtained by the study is elaborated in this text.

The average age of the patients in our study was 15.9 ± 9.9 years and average age for males and females was 17.43 ± 10.29 years and 15.17 ± 9.95 years respectively. There was no statistical significance when the average age between the genders was observed. When compared to other studies conducted by Yegin Y et al, Chow Y et al, Lameiras AR et al, Tanpowpang K et al and Yazici et al,^[4,5,6,7,8] where the average age was 6.02 years, 5.1 years, 4.3 years, 6.8 years and 5.5 years respectively, the average age in our study was higher. One of the probable reasons being the above mentioned studies were not conducted in India and the patients presenting to the tertiary care hospital would be earlier.

This also corresponds with poor health awareness and socio-economic conditions existing in the country.^[9] It can also be inferred that some of the above mentioned studies only included children as study population which corresponds to a lower mean age when compared to our study where we have included adult subjects as well. It must be kept in mind that though Otitis media with effusion predominantly occurs in children, there can be instances of it happening in teenage and adulthood due to certain pathologies such as mucociliary dysfunction, Eustachian tube pathology, adenoid infections, etc. The anatomic explanation concerning its preponderance in children is due to a horizontal position of Eustachian tube in children whereas with age the Eustachian tube elongates and angles caudally. Also developmental anomalies are detected in childhood such as cleft palate, Down's syndrome which makes one susceptible to Otitis media with effusion.^[9]

The total number of study subjects were 50 out of which 23 were females (46%) and 27 were males (53%). In a study carried out in similar subjects by Yegin Y et al,^[4] there were 78 males and 70 females. The percentage as per the gender was 52.7% for males and 47.3% females. The percentage from the said study roughly corresponds to our study. It can be deduced that there is no gender preponderance in patients suffering from otitis media with effusion.

Though there can be anatomic variations between the left and the right ear, Otitis media with effusion can be seen equally in both the ears. In our study, both the ears were equally affected.

The presenting complaints of Otitis media with effusion include ear/aural fullness, otalgia/ear pain, impaired hearing due to conduction deficit, tinnitus and associated nasal block and running nose. The vital sense organs functioning in the sensory system of hearing, smell, balance, language are affected leading to a poor quality of life.^[10]

Chow Y et al,^[5] evaluated the quality of life using OM-6 survey which measures quality of life by using some of the above mentioned parameters including physical suffering, hearing loss, speech impairment, emotional distress, activity limitations and caregiver concerns. The presenting complaints in our study included aural fullness in 32 patients, ear pain in 39 patients, impaired hearing in 38 patients, tinnitus in 14 patients, nasal block in 23 patients and running nose in 27 patients. This corresponded to aural fullness in 64%, ear pain 78%, impaired hearing in 76%, tinnitus in 28%, associated nasal block in 46%

and running nose in 54% of the study subjects. The quality of life was impaired due to the above mentioned symptoms.

The otoscopic evaluation was carried out in all the patients before proceeding with the ventilation tube insertion. The most common finding included dull lusterless amber colored tympanic membrane in 56% (n=28) of the patients, retracted tympanic membrane and foreshortened handle of malleus in 28% (n=14) of the patients, air bubbles were seen in 12% (n=6) of the subjects and fluid level was seen in 4% (n=2) of the subjects.

Cases of Otitis media with effusion are diagnosed clinically after an otoscopic examination of the ear. The use of a pneumatic otoscope helps the ENT surgeon to detect effusion in the middle ear and also check the tympanic membrane. The use of binocular microscope or telescopic video-otoscopy which are commonly used these days might improve otoscopy, particularly in children. A fluid level, air bubbles, opacity, bluish coloration and retraction of the tympanic membrane may be seen.^[11] These were evident in our study where otoscopy aided in the diagnosis based on retracted tympanic membrane, air bubbles, amber colored tympanic membrane and fluid level.

Pure tone audiometry/PTA was conducted in all the 50 patients who participated in the study. As PTA is an important indicator evaluating the hearing outcome,^[4] this formed the cornerstone for conducting our study. Pure tone audiometry was conducted pre-operatively, within one month of grommet insertion, at three months, and six months in the patients.

It is to be noted that all the patients had some amount of altered hearing which became evident on PTA, however only 38 patients had presenting complaint of impairment in the hearing corresponding to 76% of the patients.

Most of the studies conducted by other workers measured alterations in hearing due to otitis media with effusion and the common presenting complaint in all the studies was impaired hearing. Hence, much of the work is concentrated about improvement in hearing as a scale for evaluation of success of treatment in otitis media with effusion.^[12,4,5,7,13,14] The range of loss of hearing threshold in pre-operative period is summarized. A total of 11 patients had hearing loss between 0-10db, 27 had hearing loss between 11-20 db, 11 had hearing loss between 21-30 db and 1 patient had hearing loss between 30-40 db corresponding to 22%, 54%, 22% and 2% respectively.

The primary purpose of impedance audiometry is to determine the status of the tympanic membrane and the middle ear. Impedance was measured in all patients pre-operatively as an audiological test in the affected ear. It was predominately Type B in most of the patients in our study. 80% of the study participants corresponding to 40 study subjects had Type B impedance whereas the remaining 20% corresponding to 10 study subjects had Type C impedance. Tympanometric pattern was mainly type B in the pre-operative (79.3%) in a study conducted by Tanpowpong K et al,^[7] in Thai children suffering with Otitis Media with effusion which nearly matched with our study.

The pure tone audiometric reading in decibels at different intervals of time was done pre-operatively as well as post operatively. Preoperative pure tone audiometric readings were 25.9294 ± 5.86 (dB \pm SD). The pure tone audiometric readings gradually reduced post operatively, at follow up at first and third month and subsequently in the follow up at sixth months. This corresponds to improvement in the hearing capacity of the affected subjects.

A comparison was made between pre-operative values of PTA and subsequent follow ups to surgery. The readings were measured and relevant statistical tests were applied to derive the P value. Preoperative pure tone audiometric readings were 25.9294 ± 5.86 (dB \pm SD) whereas at post-operative follow up in one month it was 20.9346 ± 5.3 (dB \pm SD). The p value was 0.0000226577. The inference which can be derived from these is there is significant improvement (P<0.05) in PTA reading within 1 month subsequent to the surgery compared to pre-op values. The post-operative follow at third month PTA was 18.5402 ± 5.57 (dB \pm SD).

The p value was 0.000040688. The inference which can be derived from these is there is significant improvement ($P < 0.05$) in PTA reading at third month subsequent to the surgery compared to pre-op values. At post-operative follow at the sixth month PTA was 16.9568 ± 5.924 (dB \pm SD). The p value was 0.00000168. The inference which can be derived from these is there is significant improvement ($P < 0.05$) in PTA reading at sixth month subsequent to the surgery when compared to pre-operative values.

The p value was significant 0.0306 when values at follow up at first visit compared to follow up at third month. The inference which can be derived from these is there is significant improvement ($P < 0.05$) in PTA reading at third months compared to 1 month subsequent to the surgery. The P value was significant at 0.0006471 when compared between follow up at first visit compared to follow up at sixth month. The inference which can be derived from these is there is significant improvement ($P < 0.05$) in PTA reading at 6 months compared to 1 month subsequent to the surgery.

The p value was non-significant at 0.172 when PTA values at 3 month follow up and follow up at 6 months were compared. The inference which can be derived from these is there is non-significant improvement ($P > 0.05$) in PTA reading at 3 month and at 6 months compared subsequent to the surgery.

In study conducted by Hu S et al,^[12] a similar to ours, among patients assessed by sound field audiometry, the mean PTA value was 29.2 dB preoperatively to grommet insertion and improved to 21dB 2 weeks postoperatively and 17.9dB 6 to 10 weeks postoperatively. The difference between the two postoperative means was significant ($p < 0.0001$). This study was evaluated post operatively until 10 weeks corresponding roughly to 2 months, whereas we followed it up until after 6 months. Yegin Y et al,^[4] compared audiological outcomes of ventilation tube insertion/ Grommet insertion and myringotomy alone in association with adenoidectomy in patient with otitis media with effusion.

Their study concluded that audiological outcomes of grommet insertion were higher compared with myringotomy of tympanic membrane alone in association with adenoidectomy. Steele DW et al,^[13] conducted a meta-analysis where they concluded that Tympanostomy tubes/ Grommets improved hearing at 1 to 3 months post operatively compared with watchful waiting without surgical intervention. Tanpowpong K et al,^[7] conducted a study on audiological outcomes in Thai Children. They also concluded that myringotomy with insertion ventilation tubes could improve hearing by decreasing the air-bone gap dB. There was significant improvement in the patients treated by grommet insertion on hearing.

These above mentioned studies confirm that grommet insertion is associated with significant improvements in hearing following insertion of grommets / ventilation tubes in patients suffering from Otitis media with effusion. Our values were significant when compared to pre-operative values at all the times in follow ups extending until 6 months subsequent to surgery. Patients had extrusion of grommets at different intervals of time. Five patients had grommet extrusion within one month of insertion. Cumulatively a total of 17 patients had extrusion of grommet at three months of insertion. Subsequently at follow up at 6 months most of the patients had extrusion of grommet corresponding to 47 patients (94%). Three patients still had grommets at follow up visit at 6 months.

The study also evaluated any complications suffered by the study population. Myringosclerosis was seen in 5 patients (10%), permanent perforation was seen in 1 patient (2%). Tympanic membrane atelectasis was seen in 3 patients (6%). None of the patients had hearing loss, cholesteatoma and other complications. Considering 9 patients suffering from post-operative complications, the overall rate of complications was 18%. Complications were similar to other studies and these are expected as per available data in literature.^[15] Grommet insertion can led to infection of ear in 2 to 26% of OME patients and permanent

perforation in the tympanic membrane of these patients is seen in up to 3%. There are long-term complications of grommet insertion are tympanosclerosis in 39 to 65% of the patients, attic retraction is seen in 21% who undergo surgery, atelectasis is seen in 28% patients, segmental atrophy is seen in 16 to 75% of patients and cholesteatoma can occur in up to 1% of the patients.^[3,16]

CONCLUSION

Otitis media with effusion (OME) has varied clinical presentation; it is more common in children and adolescents without any gender preponderance. Pure tone audiometry (PTA) is an important indicator evaluating the hearing outcome and these readings gradually improved post-operatively corresponding to improvement in the hearing capacity of the affected subjects. Common post-operative complications were myringosclerosis and tympanic membrane atelectasis. Tympanostomy tube insertion is one of the ideal treatment choices for Otitis Media with effusion with significant improvement in post-operative PTA readings which can lead to a better quality of life.

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