

A Prospective Interventional study on effectiveness of Grommet insertion in Paediatric age group for Otitis Media with Effusion

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Abstract

Aim: To analyse the effectiveness of grommet insertion as treatment of otitis media with effusion in children in terms of gain in hearing and its complication.

Material and Method: A hospital based prospective study was conducted at the Department of ENT and Head & Neck surgery, Assam Medical College and Hospital, Dibrugarh, Assam which included 20 patients between age group of 5-13yrs who were clinically and audiometrically proven to be OME cases.

Results: 20 patients were included in the study. The mean air conduction preoperatively was. 3030 dB which improved to mean postoperative air conduction of 20.75dB at 12 weeks. The difference between the two means was significant ($p < 0.0001$). Mean air-bone gape (ABG) preoperatively and postoperatively was 20.30dB and 10.75dB respectively. The difference between the two means was significant ($p < 0.0001$). 5(25%) patients developed otorrhea out of which 3 patients developed perforation, 2 patient (10%)

developed retraction and 1 patient (5%) developed tympanosclerosis.

Conclusion: Grommet insertion produced significant hearing improvement in patients with OME at 12-week follow-up. Otorrhea was the most frequently found complication followed by tympanic membrane perforation in our study group. The benefits of grommet insertion must be weighed against associated complications. But, further studies with longer duration of follow up and a higher number of patients are needed to further support the findings of the study.

Clinical Significance: There are limited number of studies on this topic on Indian patients. This article could benefit many other ENT Surgeons and their patients by presenting a reliable indicator.

Keywords: Grommet insertion, Otitis media with effusion, Pure tone audiometry

Introduction

Otitis media with effusion (OME) is the chronic accumulation of mucus within the middle ear and

sometimes the mastoid air cell system. The time that the fluid has to be present for the condition to be chronic is usually taken as 12 weeks¹. In children, OME usually presents to an ENT clinic because of the associated hearing impairment and sometimes with a preceding history of illness and otalgia consequent on an episode of acute otitis media.²

While OME can occur in adults, it is mostly encountered in the pediatric population. The most frequent presenting symptoms relate to hearing loss and/or the associated impact on speech development; this may manifest as poor attention or behavioral issues. However, the condition may be silent and therefore detected only at routine hearing screening. There may be associated otalgia if there is a supervening infection, and the presence of fluid in the ear.³

Children with a cleft palate, even if repaired, have deficient palatine muscles and resultant poor Eustachian tube function. As a consequence, OME is virtually universal in infants with a cleft palate and surgical repair of their clefts does not seem to influence the incidence.²

The functional effect of OME is a conductive hearing loss of about 25-30db associated with fluid in the middle ear. Both the high incidence and high rate of spontaneous resolution suggest that the presence of OME is a natural phenomenon, its presence in some stage of childhood being a normal finding.³

The presence of middle ear fluid can be assessed on otoscopy; the tympanic membrane may be retracted and have undergone a color change, though this is variable. Otoscopy with a magnifying otoscope is very helpful, and findings of a dull tympanic membrane or a yellow/orange discoloration are typical. Also, at times there may be fluid level evident in the middle ear. The

diagnosis is confirmed on tympanometry with a Type B (a flat tracing indicating significantly reduced compliance and middle ear fluid) or C2 tympanogram (a significant negative pressure peak) indicating reduced middle ear pressure.³

Myringotomy was first performed in 1760 by Eli. It was done for the purpose of treating deafness resulting from blocked Eustachian tube. He performed myringotomy in cases of OME for improvement of deafness.⁴

The technique of inserting a hollow device through tympanic membrane to establish adequate aeration and for drainage of middle ear was first described by Politzer in 1883. Armstrong devised a plastic flanged tube in 1954. The term tympanostomy tube was first coined by Armstrong.⁵

Considerable uncertainty and controversies exists regarding the various treatment modalities of OME. The surgical treatment options include myringotomy, Ventilation tube (VT) insertion, adenoidectomy or both. Although it seems that ventilation tubes improves hearing in the short term, beneficial long term effects have been elusive. Various benefits and risks are associated with each surgical option. As untreated or improperly treated OME can cause problems in social and intellectual behavior of the child, it is of great public health importance. Considering the above facts, this study has been undertaken aiming to analyze the effectiveness of grommet insertion as treatment of otitis media with effusion in children in terms of gain in hearing and its complication.

Material And Methods

The aim of the study is to analyze the effectiveness of grommet insertion as treatment of otitis media with effusion in children in terms of gain in hearing and its complication.

This study was conducted in the department of ENT and Head and Neck Surgery in a tertiary care hospital of north east India. It was conducted from June 2018 to June 2019. Total of 20 patients were included in the study with age group of 5-13yrs (males and females both) who were clinically and audiometrically proven for having OME (Table 1). Detailed history was taken from the patients regarding onset of hearing loss, duration of hearing loss, if there was any preexisting ear pathology or any prior viral infection (Table 2). Extent of hearing loss was documented with audiometric testing (Table 3).

Ethical Clearance - Before commencing the study, necessary permission and approval from ethics committee was obtained from the Institutional Ethics Committee (Human) Ref. No. AMC/EC/PG/2551, Assam Medical College and Hospital. Informed written consents were obtained from the parent of the each patient involved in the study according to the protocol approved by the Ethics Committee and after explaining the procedure to them in their own understandable language.

Inclusion criteria

1. Between 5 and 13 years.
2. Children suffering from OME as diagnosed by impedance audiometry (Tympanometry) and Pure tone audiogram. They have taken medication for OME (antibiotics, Steroid nasal spray, systemic decongestants, antihistamines, mucolytic) at least for 12weeks but without any clinical benefit.
3. All children having associated enlarged adenoids.

Exclusion Criteria

1. Child known to have allergic rhinitis, taking medication for allergy, bronchial asthma.
2. OME caused by any reason other than adenoid hypertrophy.

3. Children with cleft palate even if repaired.
4. Children with bifid uvula, Down syndrome, Turner syndrome.
5. Child having sensori-neural hearing loss.

All the patients included in the study were pre-operatively subjected to thorough history taking, detailed clinical examination including tuning fork tests, otoscopic examination, audiometric investigation in the form of PTA (Pure Tone Audiometry) and Tympanogram & radiological investigation. Radiological investigations included x-ray nasopharynx lateral view for adenoids.

Each patient chosen for this study was initially managed with conservative approach for 3 months. But those not showing any clinical benefit were included in the study and surgical plan of management was formulated. The patients were thoroughly investigated for purpose of general anesthesia and to know the general condition of the patient.

Patient's subjective hearing was enquired and recorded on follow up at 1st and 3rd month post-operative. Post-operative pure tone audiometry and impedance audiometry (Table 3) and ear otoscopy was done in every case at the end of 1st and 3rd months. The outcome was evaluated as gain in hearing of the patient. PTA and tympanometry was done by audiologist. For MAICO-MA42 with biological calibration was used. THD30 was used in AC and Radio Ear B71 was used in BC. Tympanometry was done with MAICO-MA 42 Tympanometer. All the cases were operated under general anesthesia.

Operative Steps

Adenoidectomy: Boyles –Davis mouth gag was used to open the mouth and to retract the tongue. It was applied and mouth gag was opened gradually. Laryngopharyngeal packing was done.

Nasopharynx and adenoids were examined after retracting soft palate with curved end of tongue depressor. Adenoids were digitally palpated to assess size and to push lateral adenoid masses to midline. St. Clair Thomson's curette with guard of proper size was introduced into nasopharynx and posterior border of nasal septum was felt. Adenoids were shaved with gentle sweeping movement of curette while maintaining slight flexion of head. Hemostasis was achieved with packing.

The pinna and the external auditory canal wall was cleaned and sterilized with rectified spirit (35%). Myringotomy was performed under general anesthesia. Under magnification of microscope, a radial incision was given at the antero-inferior quadrant of the tympanic membrane of affected side with a myringotome. The incision was given near umbo. The middle ear effusion was aspirated as much possible shifting the tip of the micro-suction in different angles. Ventilation tube was inserted in antero-inferior quadrant. Tympanostomy tube is held at its one end with an (micro crocodile forceps/grommet inserter) and the other end was introduced into the myringotomy incision. Medially directing end of the tube was pressed at its one part of flange followed by pushing the other. Fitting and positioning of the tube was confirmed. A Neosporin cotton pack was applied into the external auditory meatus after completion of the procedure.

Antibiotic was continued till 5th post-operative day. A combination of third generation cephalosporin with sulbactam or amoxicillin with clavulonic acid was used in the majority of the cases. Along with it, analgesic, anti-inflammatory syrup/tab, nasal decongestant drop were prescribed post operatively for 5 days. Water precautions were maintained for six weeks & patients were advised to abstain from forceful nose blowing,

exposure to cold & swimming. The patients were advised to report after fourth and 12th week post-operative. At time of checkup, TM examination, PTA and impedance audiometry were done.

Statistical Analysis

Data were evaluated using descriptive statistical methods using Microsoft Excel and Graphpad website. Quantitative data were presented as mean and standard deviation. Qualitative variables were presented as percentages. Paired 't' test was performed to test the differences in pre-operative and post-operative audiological outcome in terms of gain of hearing. The qualitative data were compared using chi-square test and Fisher test. In these tests, p-value <0.05 was considered statistically significant.

Results

Among 20 patients selected for the study most of the patients belong to the age group of 5-7 years (35 %). Lowest number of patients were from age group of 13-15 years(10%). The overall mean age of the patients in the study was $8.55y \pm 2.67SD$ (Table 1).

In the study, 11 patients (55%) were male and 9 patients(45%) were female. The male and female ratio was 1.22:1. There were 14 patients with left ear and 6 patients with right ear involvement.

Majority of patients in the study belong to class IV i.e. 6 patients (30%). Class II, V, I and III included 4 (20%), 4 (20%), 3 (15%) and 3 patient (15%) respectively. 60% of patients presented with impairment of hearing. Fullness of ear was found in 40% patients, mouth breathing in 35% patients, sleep fragmentation in 50% patients and least common symptom was earache in 20% patients. Retracted tympanic membrane, bulged tympanic membrane, air fluid level and air bubbles was seen in 9,5,10 and 4 patients respectively. 5 patients (25%) had immobile

ear drum and 15 patients (75%) had mobile ear drum (Figure 2).

18 patients (90%) showed B type curve and 2 patients(10%) showed c type curved.60% had mean air conduction in the range of 21-30dB and 40% had mean air conduction in the range of 31-40dB. 60% had mean air bone gap in the range of 11-20dB and 40% had mean air bone gap in the range of 31-40dB. Bone conduction (BC) was in the range of 0-10 dB for all the patients included in the study. The mean pre-op AC (in dB) was $30.30 \pm 2.90SD$. The mean pre-op ABG (in dB) was $20.30 \pm 2.90SD$

The post-operative PTA findings 45% had mean air conduction in the range of 11-20dB and 55% had mean air conduction in the range of 21-30dB. 45% had mean air bone gap in the range of 0-10dB and 55% had mean air bone gap in the range of 11-20dB.The mean post-op AC was $20.75dB \pm 3.51 SD$. mean post -op ABG was $10.75dB \pm 3.51SD$. The gain in hearing was $9.55 \pm 3.71SD$

5 (25%) patients developed otorrhea, 4 (20%) patient develops perforation, 2 patient (10%) develops retraction and 1 patients (5%) develops tympanosclerosis. Out of 20 patients 16 patients(80%) had spontaneous extrusion of grommet by 3rd month. In the remaining 4 patients(20%) grommet was removed surgically (Table 4).

Discussion

Otitis media with effusion is very common in paediatric age group with a prevalence The prevalence of OME is rather variable, ranging from 1.3 to 31.3%, depending on the methods used, population characteristics like race, countries and environmental factors^{6,8,9}. OME is defined as the accumulation of fluid in the middle ear cavity without any signs of acute infection middle ear effusion without signs or symptoms of an acute

infection. OME may occur as a primary disorder or as a sequel to acute otitis media. The functional effect of OME is a conductive hearing level of around 30 dB associated with fluid in the middle ear. The most common medical treatment options include the use of decongestants, mucolytics, steroids, antihistamines and antibiotics . The effectiveness of these therapies has not been established. Surgical treatment options include grommet (ventilation or tympanostomy tube) insertion, adenoidectomy or both. Opinions regarding the risks and benefits of grommet insertion vary greatly. The management of OME therefore remains controversial⁷. The aim of the study is to analyse the effectiveness of grommet insertion as treatment of otitis media with effusion in children in terms of gain in hearing and its complication.

This study was conducted in the department of ENT and Head and Neck Surgery, Assam Medical College and Hospital,Dibrugarh which is a tertiary referral centre . It was conducted from June 2018 to June 2019. Total of 20 patients were included in the study with age group of 5-13yrs (males and females both) who were clinically and audiometrically proven for having OME. Detailed history was taken from the patients regarding onset of hearing loss, duration of hearing loss, if there was any preexisting ear pathology or any prior viral infection. Extent of hearing loss was documented with audiometric testing.

Shishegar M, et al in their study illustrated that the mean age at initial tube placement of children not requiring a second set of tubes = 35.9 months¹⁰.In our study overall mean age of the patients in the study was $8.55y \pm 2.67SD$, with highest percentage of patients belonging to the age group of 5-7 years (35 %).11 patients (55%) were male and 9 patients(45%) were female. The male and female ratio was 1.22:1.

Hearing loss, although not always present, is the most common complaint in OME patients, parents may also complain of communication difficulties, withdrawal, and lack of attention. Earache, can be intermittent in these patients. In many instances, they will have the symptom of aural fullness.

T. Bandyopadhyay et al in their study found presenting complaints among controls were rhinitis and mouth breathing 10 each (20% each), sore throat 9 (18%), nose bleed 5 (10%), nose block 4 (8%), ear block 3 (6%), neck swelling 2 (4%), decreased response, noisy breathing, tongue tie, foreign body in nose, itching in the ear, ear bleed, cough: 1 each (2% each) ¹¹.

In our study 60% of patients presented with impairment of hearing. Fullness of ear was found in 40% patients, mouth breathing in 35% patients, sleep fragmentation in 50% patients and least common symptom was earache in 20% patients.

Lee DH et al in their study mentioned that the status of middle ear of 51 children (85 ears) from November 2002 to February 2003 was examined using pneumatic otoscopy, otomicroscopy, and tympanometry, and the presence/absence of middle ear effusion was confirmed by myringotomy. The otomicroscopy was the most sensitive and specific one among three diagnostic tools ¹².

In our study Otoscopic finding of retracted tympanic membrane, bulged tympanic membrane, air fluid level and air bubbles was seen in 9,5,10 and 4 patients respectively. In our study 15 patients had mucoid effusion and 5 patients had serous effusion. Overall most commonest type of effusion was mucoid effusion. Muhammad Javed Aslam et al. in their study found that the degree of preoperative hearing loss was mild (20-40 dB) in 4(8.9%) ears, moderate (40-60 dB) in 39(86.7%) ears and severe (60-80 dB) in 2(4.4%) ears. Patients

were re-evaluated and pure tone audiograms were obtained after grommet insertion. The degree of post-operative hearing loss was mild (20-40 dB) in 35 (77.8%) ears, moderate (40-60 dB) in 10(22.2%) ears and severe (60-80 dB) in none. No improvement in hearing was noted in 11(24.4%) ears, 5-10 db improvement was noted in 29(64.4%) ears and 10-20 dB improvement was noted in 5(11.1%) ears. There was a statistically significant difference in the pre-operative and post-operative hearing loss in the ears, the hearing loss was significantly lower after grommet insertion; $p=0.016$ ¹³.

In our study 60% had mean air conduction in the range of 21-30dB and 40% had mean air conduction in the range of 31-40dB. 60% had mean air bone gap in the range of 11-20dB and 40% had mean air bone gap in the range of 31-40dB. Bone conduction (BC) was in the range of 0-10 dB for all the patients included in the study. The mean pre-op AC(in dB) was $30.30 \pm 2.90SD$. The mean pre-op ABG (in dB) was $20.30 \pm 2.90SD$. 18 patients (90%) showed B type curve and 2 patients (10%) showed c type curved. Majority of patients showed B type curve in tympanogram. Nurliza et al. in their study noted that type B tympanometry was seen in 74%, type A in 14% and type C in 12 % of patients ¹⁴. Lildholdt in his study 56% patients showed B type curve, 43% showed C type curve and 1% showed A type of curve ¹⁵. Tuli et al. in their study on evaluation of tympanostomy tubes in middle ear affections found that in 60% cases type B curve was seen but in remaining 40% cases type C curve was found ¹⁶.

Post-operative PTA findings 45% had mean air conduction in the range of 11-20dB and 55% had mean air conduction in the range of 21-30dB. 45% had mean air bone gap in the range of 0-10dB and 55% had mean air bone gap in the range of 11-20dB. The mean post-op

AC was $20.75\text{dB}\pm 3.51$ SD. Mean post-op ABG was $10.75\text{dB}\pm 3.51$ SD. The gain in hearing was 9.55 ± 3.71 SD

Yaman H. et al. in their study found that complications after tympanostomy tube extrusion included myringosclerosis (34.6%), persistent perforation (5.6%), atrophy (23.5%), retraction (16.7%) and medial displacement of tubes (1.2%). The average extrusion time was 8.5 ± 4.6 months (range 1-24) for Shepard grommet tympanostomy tubes¹⁷.

Erdogljija *et al.* suggested that one of the reasons for premature extrusion of TT was iatrogenic, such as too big myringotomy, which can be avoided by careful otomicroscopy work. In four (1%) ears there was recurrence of OME and the patients were prepared for another operation using T-type tube.¹⁸

In our study 5 (25%) patients developed otorrhea, 4 (20%) patient develops perforation, 2 patient (10%) develops retraction and 1 patients (5%) develops tympanosclerosis. Out of 20 patients 16 patients (80%) had spontaneous extrusion of grommet by 3rd month. In the remaining 4 patients (20%) grommet was removed surgically.

Conclusion

Grommet insertion produced significant hearing improvement in patients with OME at 12-week follow-up. Otorrhea was the most frequently found complication followed by tympanic membrane perforation in our study group. The benefits of grommet insertion must be weighed against associated complications. But, further studies with longer duration of follow up and a higher number of patients are needed to further support the findings of the study.

Clinical Significance

There are limited number of studies on this topic on Indian patients. This article could benefit many other

ENT Surgeons and their patients by presenting a reliable indicator.

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Legend Tables and Figure

Age(In Years)	(n=20)	
	No.	%
5--7	7	35
7--9	3	15
9--11	5	25
11--13	3	15
13--15	2	10
Mean Age In Years	8.55±2.67	

Table 1: Age wise distribution of patients

Clinical	(n= 20)	
	No.	%
Impairment Of Hearing	12	60
Fullness Of Ear	8	40
Earache	4	20
Mouth Breathing	7	35
Frequent Arousal/ Sleep Fragmentation	10	50

Table 2: Distribution of clinical presentations

	PRE-OP HEARING (dB)				POST-OP HEARING(dB)			
	Air conduction (AC)		ABG		Air conduction (AC)		ABG	
	No.	%	No.	%	No.	%	No.	%
0-10	0	0	0	0	0	0	9	45
10-20	0	0	12	60	9	45	11	55
20-30	12	60	8	40	11	55	0	0
30-40	8	40	0	0	0	0	0	0

40-50	0	0	0	0		
Mean	30.30±2.90SD		20.30±2.90SD		20.75±3.51	10.75±3.51

Table 3: Comparison of pre-operative and postoperative hearing loss

Complications		
	No.	%
Otorrhea	5	25
Perforation	4	20
Retraction	2	10
Tympanosclerosis	1	5
SPONTANEOUS EXTRUSION	16	80

Table 4: distribution of postoperative complications

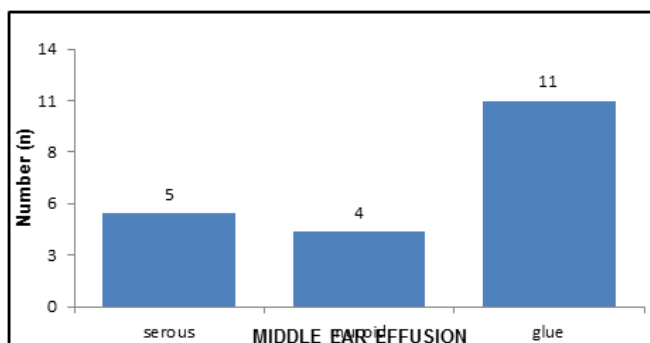


Figure 1: types of discharge in OME cases

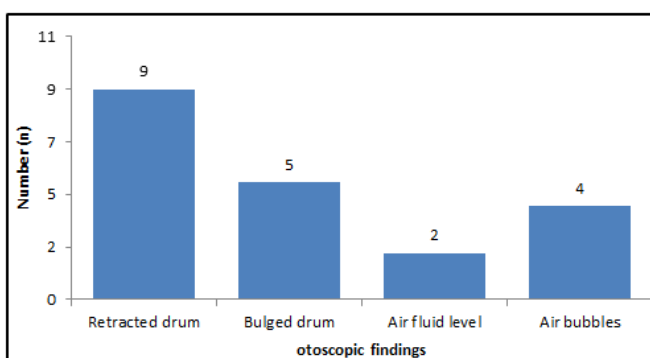


Figure 2: Otoscopic findings of OME cases