A Prospective Controlled Study on Outcomes of Medical and **Surgical Treatment of OTITIS Media with Effusion**

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Abstract: Introduction: Otitis media with effusion 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 weeks. In many children OME is usually preceded by an episode of acute otitis media with otalgia and fever particularly so in younger children because of their greater propensity to upper respiratory tract infections. This damages the Eustachian tube epithelium with resultant retention of middle ear fluid.

Materials and Methods: The study was conducted in a tertiary care hospital and is a non-randomised controlled, prospective study. Sample size was taken conveniently. A total number of 100 patients from age 5-30 years, suffering from persistent otitis media with effusion and adenoid hypertrophy were selected from the outpatient department of ENT after detailed clinical examination and investigations. Exclusion criteria involves patients with OME but no adenoid hypertrophy, previous history of any surgery for this condition, suspected neoplastic lesion of posterior nasal space, presence of craniofacial abnormality and any history of radiotherapy in the region concerned. Patients were serially placed according to the date of registration in three groups. Group 1 was subjected to medical management with antibiotics and short-term steroid therapy. Group 2 underwent myringotomy and grommet insertion and Group 3 underwent myringotomy and grommet insertion along with adenoidectomy or adenotonsillectomy.

Results: A total number of 100 patients with age distribution of 50% in the age group of 5-9 years, 20% in 10-14 years and 30% in 15-30 years. Males were predominant in the study. Hearing improvement was assessed after completion of the treatment. Paired T-tests were done for each treatment group and it was found that pretreatment and post-treatment A/B gaps improvement were significant for treatment Group 2 and Group 3.

Conclusion: The myringotomy plus grommet insertion along with adenoidectomy/adenotonsillectomy gave equivocal outcomes as myringotomy with grommet insertion alone. Adenoidectomy/adenotonsillectomy is effective surgical procedure to improve Eustachian tube function and hearing in children when indicated. *Key Words: Otitis media, Eustachian tube epithelium, myringotomy*

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I. Introduction

Otitis media with effusion 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 weeks. In many children OME is usually preceded by an episode of acute otitis media with otalgia and fever particularly so in younger children because of their greater propensity to upper respiratory tract infections. This damages the Eustachian tube epithelium with resultant retention of middle ear fluid.

OME has a lower prevalence in adults and is then frequently associated with other underlying diagnoses. Finkelstein et al2 described paranasal sinus disease as the dominant factor in 66% of adults with OME.

The clinical features include a history of hearing difficulties, poor attention, behavioural problems, delayed speech and language development, clumsiness and poor balance. Otoscopic findings are observable airfluid levels, serous middle ear fluid and a translucent membrane with diminished mobility. Extensive inflammation and purulent middle ear effusion should not be evident. The negative pressure is suggested by the prominence of the lateral process, a more horizontal orientation of the malleus and movement only with negative pneumatoscopy. Tonsillar hypertrophy can accompany the more commonly adenoid hypertrophy, especially in patients with prolonged or recurrent condition.

Pure tone audiometry and tympanometry is perhaps the most useful of all tests in association with otitis media with effusion (OME). Tympanometry usually reveals a type B result (Flat) or a type C result (Negative pressure), while pure tone audiometry reveals a conductive hearing loss with wide air-bone gap.

In general, AOM follows a favourable course without antibiotic treatment with analgesia and antipyretics being important.3-5 Decongestants and antihistamines, local intranasal steroids have been traditionally used for the treatment of OME.

When OME is bilateral and persistent for more than 3 months, the chances of natural resolution are much lower and treatment may be beneficial.6-7

Surgery is recommended for persistent disease with significant hearing loss causing morbidity. In previous studies, Myringotomy and aspiration of the fluid showed some improvement of hearing. Grommet tubes are available in a variety of sizes, shapes and materials. All are designed to permit ventilation of the middle ear and mastoid system. Prolonged aeration of the middle ear has been shown to reverse the mucosal hyperplasia and metaplasia that accompany otitis media with effusion. Thereby in present study, we tried to find out how much improvement in hearing is achieved when myringotomy and grommet insertion procedure is done supplemented with adenoidectomy or adenotonsillectomy.

II. Materials And Methods

The study was conducted in a tertiary care hospital and is a non-randomised controlled, prospective study. Sample size was taken conveniently.

A total number of 100 patients from age 5-30 years, suffering from persistent otitis media with effusion and adenoid hypertrophy were selected from the outpatient department of ENT after detailed clinical examination and investigations.

Exclusion criteria involves patients with OME but no adenoid hypertrophy, previous history of any surgery for this condition, suspected neoplastic lesion of posterior nasal space, presence of craniofacial abnormality and any history of radiotherapy in the region concerned.

Patients were serially placed according to the date of registration in three groups. Group 1 were subjected to medical management with antibiotics and short-term steroid therapy. Group 2 underwent myringotomy and grommet insertion along with adenoidectomy or adenotonsillectomy.

A follow-up of 6 months was done at an interval of two weeks to determine the symptomatic improvement and status of grommet. The PTA and tympanometry were repeated at one month and three months post-operative period and evaluated.

The outcomes of each group were studied statistically using the SPSS v16.0, (ANOVA test, paired T-test, Bonferroni post-hoc test), MS Excel etc.

III. Results

A total number of 100 patients with age distribution of 50% in the age group of 5-9 years, 20% in 10-14 years and 30% in 15-30 years. Males were predominant in the study. Hearing improvement was assessed after completion of the treatment.

S.No	Group	Pre-Treatment A/B Gap	Post-Treatment A/B Gap	Improvement
1	Group 1 (N=25)	13.56±6	12±4	2.32±5
2	Group 2 (N=27)	22.32±7	13.65±6	8.92±6
3	Group 3 (N=23)	24.28±8	16±7	9.35±6

Table 1: Hearing Results

Paired T-tests were done for each treatment group and it was found that pre-treatment and post-treatment A/B gaps improvement were significant for treatment Group 2 and Group 3.

S.No	Parameter	Group 1	Group 2	Group 3	P Value		
1	Post-Treatment A/B Gap	12±4	14.23±6	16±5	0.000		
 Table 2: Dost treatment overall outcome							

Table 2: Post treatment overall outcome

S.No	Treatment Group (a)	Comparison Group (b)	Mean Difference in a/b Closure (a-b)	P Value
1	Group 1	Group 2	-6.76	0.000
2		Group 3	-7.54	0.001
3	Group 2	Group 1	6.54	0.000
4		Group 3	-0.52	1.000
5	Group 3	Group 1	7.35	0.001
6		Group 2	0.42	1.000

Table 3: Post treatment comparison between Groups

On further analysis with help of Bonferroni (post-hoc) test, significant results were found when medical treatment group was compared to surgical treatment groups, but there was no difference found in additional surgery done in Group 3 (Adenoidectomy and/ or tonsillectomy) when compared to myringotomy and tympanostomy tube insertion alone (Group 2).

Post-operative complication at the end of 6 months follow-up visit were tube blockage (8%), tube extrusion (6%), ear discharge (12%) and dry perforation (4%).

IV. Discussion

The present study was carried out to document the clinical and audiological outcomes of patients managed conservatively and surgically.

Current studies do not support routine use of antihistamines and decongestants in children with OM, but they might be used for treatment of specific patients such as those with OME due to allergies.8 Antimicrobial therapy may provide at least short-term relief for symptomatic children (Hearing loss, developmental delay, etc.) for whom surgery must be postponed or is contraindicated.9 There is evidence of both benefits and harms associated with the use of oral antibiotics to treat children up to 16 years with OME and were not associated with fewer ventilation tube insertions.10 American Academy of Otolaryngology 2016 update recommends against using intranasal or systemic steroids, systemic antibiotics and antihistamines, decongestants or both for treating OME.11 The use of medical treatment showed no significant improvement in the present study as well.

According to the present guidelines, clinicians should offer bilateral tympanostomy tube/ grommet insertion to children with bilateral OME for 3 months or longer (Chronic OME) and documented hearing difficulties. They also should offer bilateral tympanostomy tube insertion to children with recurrent AOM, who have unilateral or bilateral middle ear effusion at the time of assessment for tube candidacy. Lieberthal AS, Carroll AE et al suggests both ventilation tubes and prophylactic antibiotics are only effective for the duration of ventilation tube stay time (most ventilation tubes extrude 6-9 months after placement) or for as long as antibiotics are taken, respectively.12 In our present study, we found significant outcomes on myringotomy and tympanostomy tube insertion as hearing levels improved and were symptomatically relieved.

Ventilation tube insertion is associated with a number of risks which include purulent otorrhoea, myringosclerosis (most common), retraction pockets and persistent tympanic membrane perforations.13 In addition, once tubes extrude OME may return with one trial of short-term tubes noting that a quarter of children requiring a second set of ventilation tubes within 2 years.14 Ear discharge was found to be most common complication post TT placement in our study.

V. Conclusion

The myringotomy plus grommet insertion along with adenoidectomy/adenotonsillectomy gave equivocal outcomes as myringotomy with grommet insertion alone. Adenoidectomy/adenotonsillectomy is effective surgical procedure to improve Eustachian tube function and hearing in children when indicated.

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