

## COMPARATIVE STUDY ON OUTCOMES OF MEDICAL AND SURGICAL TREATMENT OF OTITIS MEDIA WITH EFFUSION

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### ABSTRACT

#### BACKGROUND

Otitis media with effusion is a common childhood disorder, which resolves on its own in a few months. Recurrence or persistence of the disease warrants treatment with medical or surgical intervention according to the severity. Recent recommendations suggest no role for antihistamines, decongestants or antibiotics leading to various other problems like antibiotic resistance. Already established surgical management commonly involves myringotomy with grommet insertion with or without adenoidectomy and adenotonsillectomy and is now the preferred modality of treatment. This article compares the outcomes of surgical treatment with that of medical management.

The aim of this study is to assess the outcomes of surgical treatment outcomes compared to the medical treatment of otitis media with effusion.

#### MATERIALS AND METHODS

The study was conducted in a tertiary care hospital and is a non-randomised, controlled, prospective study. A total number of 70 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. The study is of a prospective, non-randomised type where the sample of patients who were included in the study were divided into three different groups depending on the mode of management. The parameter to measure the outcomes were obtained from the improvement of air-bone gap pre and post-treatment. The comparisons of outcomes were made using statistical tools. In this study, we found that surgical management with myringotomy and grommet insertion alone to be as effective as with additional adenoidectomy/adenotonsillectomy and had statistically better results than medical management. The author suggests adenoidectomy/adenotonsillectomy only in cases indicated, but not to be done routinely. For long-standing or recurrent otitis media with effusion, myringotomy with grommet insertion (surgical treatment) is the preferred choice of treatment.

#### RESULTS

A total number of 70 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.

#### CONCLUSION

The myringotomy plus grommet insertion along with adenoidectomy/adenotonsillectomy gave equivocal outcomes as myringotomy with grommet insertion alone.

#### KEY WORDS

Otitis Media with Effusion, Surgical Management.

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#### BACKGROUND

Otitis media with effusion syn. 'Glue Ear' is best defined as the presence within the middle ear cleft of an effusion which may be serous, mucoid, serosanguinous with intact tympanic membrane.

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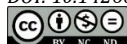
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It results from a dysfunction of the mucociliary system of the middle ear cleft causing negative pressure and accumulation of fluid. Many factors have been implicated in the failure of the clearance mechanism including ciliary dysfunction, mucosal oedema, hyperviscosity of the effusion and possibly an unfavourable pressure gradient. The classic explanation proposes that eustachian tube dysfunction is the necessary precursor. In long-standing dysfunction, the negative pressure elicits a transudate from the mucosa leading to the eventual accumulation of a serous, essentially sterile effusion. Young children are more prone to AOM and OME due to an anatomical predisposition. The eustachian tube is shorter, more flexible and horizontal, which allows nasopharyngeal pathogens to enter the middle ear with relative ease.<sup>1</sup> The newer theories supports the primary

event, as inflammation of the middle ear mucosa caused by a reaction to bacteria already present in the middle ear. Once the acute inflammation and bacterial infection have resolved, a failure of the middle ear clearance mechanism allows middle ear effusion to persist. The commonly found bacteria in order of frequency are *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Moraxella catarrhalis*.

OME has a lower prevalence in adults and is then frequently associated with other underlying diagnoses. Finkelstein et al<sup>2</sup> 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 air-fluid 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.<sup>3-5</sup> 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.<sup>6-7</sup>

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.

The complications associated with grommet insertion include persistent otorrhoea, which is the most common complication occurring in 15% of patients and persisting as long as 1 year in 5% of patients. Tympanosclerosis, which is not likely to be clinically significant unless it is extensive, persistent perforation, granulation tissue formation, cholesteatoma and sensorineural hearing loss are among the other complications with grommet.

**Objective**

The aim of this study is to assess the outcomes of surgical treatment outcomes compared to the medical treatment of otitis media with effusion.

**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 70 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 and Group 3 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.

**RESULTS**

A total number of 70 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.

Group	Pre-treatment A/B Gap	Post-treatment A/B Gap	Improvement
Group 1 (n=20)	14.00+/-5SD	12.00+/-4SD	2.00+/-5SD P = 0.104
Group 2 (n=34)	23.23+/-7SD	14.41+/-5SD	8.82+/-5SD P=0.000
Group 3 (n=16)	24.37+/-8SD	15.00+/-6SD	9.37+/-6SD P=0.000

**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.

	Group 1	Group 2	Group 3	P value
Post-treatment A/B gap	12+/-4SD	14.41+/-5SD	15+/-6SD	0.000

**Table 2. Post-Treatment Overall Outcome**

The post-treatment overall comparison of A/B gap closure using ANOVA test was found significant.

Treatment Group (a)	Comparison Group (b)	Mean Difference in a/b Closure (a-b)	P value
Group 1	Group 2	-6.82	0.000
	Group 3	-7.37	0.001
Group 2	Group 1	6.82	0.000
	Group 3	-0.55	1.000
Group 3	Group 1	7.37	0.001
	Group 2	0.55	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%).

## DISCUSSION

Otitis Media with Effusion (OME) is characterised by a non-purulent effusion of the middle ear that may be either mucoid or serous. Otitis media with effusion (OME) is the leading cause of hearing loss in children. Pharmacologic management of otitis media with effusion (OME) includes administration of antimicrobial agents, steroids, antihistamines and decongestants and mucolytics. Among the surgical options, myringotomy with grommet insertion with or without adenoidectomy or adenotonsillectomy are usually undertaken.

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.<sup>8</sup> 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.<sup>9</sup> 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.<sup>10</sup> American Academy of Otolaryngology 2016 update recommends against using intranasal or systemic steroids, systemic antibiotics and antihistamines, decongestants or both for treating OME.<sup>11</sup> 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.<sup>12</sup> 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.<sup>13</sup> 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.<sup>14</sup> Ear discharge was found to be most common complication post TT placement in our study.

Adenoidectomy is also thought to have a role in preventing recurrent OME,<sup>15</sup> but due to associated risks it is typically not recommended as a primary treatment of OME, unless there are frequent or persistent upper respiratory tract infections. Adenoidectomy +/- tonsillectomy played as an adjuvant role in our study as the results were found to be significant when compared to medical treatment, but was not found to be superior to myringotomy and grommet placement alone.

Recent advances in the fields of microbiology, biofilm study, vaccine developments, genetics and drug delivery to middle ear offer the potential for better treatments in the future.<sup>16</sup>

## 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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