

# Efficacy of Medical and Surgical Management in Otitis Media with Effusion in Children: A Comparative Study

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## ABSTRACT

**Background:** Otitis media with effusion (OME) is a common disease seen in 90% of children before going to school. The management of the condition includes both medical management and surgical management. Thus, a randomized control study was conducted in the Department of Otorhinolaryngology, Regional Institute of Medical Sciences, Imphal, Manipur, India from 2014 to 2016, in which 126 cases of newly diagnosed case of OME from 4 to 14 years of age were included. Patients were divided into two groups randomly. One group was treated by medical therapy alone and the other group by surgical therapy only. Patients were followed up every 2 weeks for the first 2 months and then every month for the next 3 months and symptoms along with pure-tone audiometry and Impedance audiometry were noted. Symptoms, pure-tone audiogram, and impedance audiometry in the first and third months were compared with the initial readings.

**Result:** In this study, we found pre-intervention mean air-bone (AB) gap was found to be  $27 \pm 4.6$  dB in the medical arm while  $28.5 \pm 5.9$  dB was found in the surgical arm. Following medical and surgical management of patients, the mean AB gap at 1 month period was  $18 \pm 2.7$  dB in the medical arm and  $15 \pm 4.2$  dB in the surgical arm. Similar trends were seen at 3 months postintervention in which the mean AB gap was  $16 \pm 2.5$  dB in the medical arm and  $9.04 \pm 2.4$  dB in the surgical arm. The findings were found to be statistically significant ( $p < 0.05$ ).

**Conclusion:** Improvement in hearing and reduction in the AB gap is more in the surgical group during the third month.

**Clinical significance:** The study was conducted to compare the outcomes of the surgical and medical management of OME as it poses a great risk to children who are the building blocks of society.

**Keywords:** Antihistaminics, Antimicrobials, Corticosteroid, Decongestants, Grommet, Myringotomy, Otitis media with effusion, Randomized control study.

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## INTRODUCTION

Otitis media with effusion or glue ear is the chronic accumulation of mucous within the middle ear and mastoid air cell system.<sup>1</sup> Otitis media with effusion is one of the most common diseases among infants and children, with more than 90% of children experiencing OME before reaching school age.<sup>2,3</sup> By the age of 4 years, approximately 80% of children will have had an episode of OME, and most of these resolve within 6–10 weeks. The most important etiologic factors for OME are infection, inflammation, and insufficient pneumatization of the middle ear. Conditions such as eustachian tube dysfunction, insufficient pneumatization of the mastoid, craniofacial abnormalities, infections, immunodeficiency, and allergic agents are among the controversial causes of OME.<sup>4</sup> The updated 2004 guidelines offer several recommendations, including watchful waiting for 3 months, and issue recommendations related to the avoidance of antihistamines, decongestants, antimicrobials, and corticosteroids.<sup>5</sup> Topical intranasal corticosteroids have evidence of efficacy from several small clinical trials as well as theoretical reasons to support further evaluation.<sup>6,7</sup> Anti-inflammatory effects on the postnasal space, the peritubal lymphatic tissue, and encroaching adenoids have all been suggested.<sup>6</sup> The insertion of grommets (ventilation or tympanostomy tubes) into the ear drum is one of the most common operations in childhood for OME. The primary indication for the operation is the restoration of normal hearing in children with long-standing (more than 3–6 months) bilateral OME. Other indications for grommets are the prevention of recurrent acute otitis media and earache (otalgia).<sup>8</sup> The rationale for

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the procedure is to improve ventilation and pressure regulation in the middle ear.<sup>9</sup> The effect of myringotomy alone is very short lived. The mean function time of the most commonly used grommets (Armstrong, Shepard) is 6–12 months.<sup>8</sup> The aim of this study was to assess the difference in the surgical and medical outcomes of OME.

## METHODS

A randomized control study was conducted in the Department of Otorhinolaryngology, Regional Institute of Medical Sciences,

**Table 1:** AB gap in surgical and medical arms before and after treatment

	ABgap		
	Pretreatment (dB)	At 1 month post-treatment (dB)	At 3 months post-treatment (dB)
Surgical arm	28.5 ± 5.9	15 ± 4.2	9.04 ± 2.4
Medical arm	27 ± 4.6	18 ± 2.7	16 ± 2.5

Imphal, Manipur, India from 2014 to 2016, in which all diagnosed cases of OME from 4 to 14 years of age were included. A total of 126 cases of secretory otitis media (bilateral/unilateral) OME, were included in the study. Patients with a history of chronic otitis media and with mixed or pure sensorineural hearing loss who had undergone previous ear surgery were excluded from the study. Written informed consent was taken from all participants and approval from the institutional ethics committee of the Regional Institute of Medical Sciences, Imphal, Manipur, India was taken before starting the study.

Diagnosis of OME was made on a detailed clinical, otoscopic examination after taking proper history. Pure-tone audiogram and Impedance audiometry were done in all patients to document the degree and type of hearing loss. Also, X-ray of nasopharynx lateral view was taken to see if there were adenoids. Patients have divided into two groups randomly according to computer-generated random number (Table 1) as study subjects. One group was treated by medical therapy alone and the other group by surgical therapy only. In the medical arm, patients were treated with oral antibiotics, and oral antihistaminics 5 mL once daily for 10 days. Antibiotic therapy oral antibiotic amoxicillin-clavulanate (45 mg/kg/day) for 7 days, nasal decongestants (2 drops 2 times for 5 days), and topical nasal steroids (mometasone furoate) one puff in each nostril once daily for 3 months. While patients in surgical arms were treated by myringotomy and grommet insertion under general anesthesia. Myringotomy was done in anteroinferior quadrant of the tympanic membrane followed by placement of Shepard-type grommet insertion. The patient underwent adenoidectomy if adenoids were found enlarged. Patients were discharged 24 hours after the procedure.

Patients were followed up every 2 weeks for the first 2 months and then every month for the next 3 months and symptoms along with pure-tone audiometry and Impedance audiometry were noted. Symptoms, pure-tone audiogram, and impedance audiometry at first and third months were compared with the initial readings. The main outcome measures were improvement in hearing which is confirmed by PTA, and impedance audiometry findings, improvement in symptoms, and failure of treatment.

### Statistical Analysis

The data collected from the study were analyzed using IBM SPSS, version 21. Descriptive statistics such as mean and percentages were used. Chi-squared test, *t*-test, and ANOVA were used for the test of significance. A probability value of less than 0.05 was taken as significant.

### RESULTS

A total of 126 patients were included in the study out of which 63 patients were randomly divided into both arms, that is, medical and surgical arms, respectively. The mean age in the medical group was 8.71 ± 2.2 while in the surgical group it was 8.5 ± 2.4 years. Out of 63 in the medical group, 34 were females and 29 were males; however, in the surgical group, 27 were females and 36 were males. The majority of the patients belonged to middle and lower

socioeconomic status according to the modified Kuppaswamy scale (65.1%). Among 126 patients, the decreased hearing was the most common presenting symptom seen in 100% followed by aural fullness in 88.1%, earache in 37.3%, and tinnitus in 14.2% of patients. A total of 34.1% patients had a past history of nasal blockage, running nose, and snoring while 14.3% of patients had a positive history of parental smoking. Pre-intervention means AB gap was found to be 27 ± 4.6 dB in the medical arm while 28.5 ± 5.9 dB was found in the surgical arm. Following medical and surgical management of patients, the mean AB gap at 1 month period was 18 ± 2.7 dB in the medical arm and 15 ± 4.2 dB in the surgical arm. Similar trends were seen at 3 months postintervention in which the mean AB gap was 16 ± 2.5 dB in the medical arm while 9.04 ± 2.4 dB in the surgical arm as seen in Table 1. The findings were found to be statistically significant (*p* < 0.05).

### DISCUSSION

In the literature, the secretory otitis media is known by a variety of synonyms like middle ear effusion, serous otitis media, glue ears, chronic non-suppurative otitis media, chronic OME and simply OME.<sup>10</sup> We included 126 patients out of which half were treated by medical management while another half by surgical management.

In our study, we found that majority of patients belonged to middle and lower socioeconomic groups similar to the findings of Siddharta et al. in their study. The probable reasons for the higher number might be the poor hygiene standards in this population, overcrowding in these families and most importantly poor nutritional status of these children.<sup>11</sup>

Similar to our study, Najeef et al. also reported decreased hearing in 100% of patients. Aural fullness was the next common symptom followed by earache with 88.1 and 37.3% prevalence, respectively. Malik et al. in their study also found similar results with a prevalence of 77.5 and 37.5%, respectively.<sup>10</sup> We also reported tinnitus in 14.2% of patients however contrary to this Tuli et al. reported tinnitus in 36% of cases.<sup>12</sup>

In our study, we found that the AB gap improved more in the surgical group at the first and third month postintervention as compared to patients of medical group. Mean AB gap was 28.5 ± 5.9 and 27 ± 4.6 dB in the surgical and medical group pre-intervention, respectively. While AB gap at the first month postintervention was 15 ± 4.2 dB and 18 ± 2.7 dB in surgical and medical groups, respectively, which further improved to 9.04 ± 2.4 and 16 ± 2.5 dB in third month of post-intervention, respectively. Sharath et al. compared the mean AB gap reduction from pre- and post-myringotomy and grommet insertion after 3 months and found that the improvement in AB gap was statistically significant.<sup>13</sup> However, Mohammad et al found that the reduction of AB gap in pre- and post-medical therapy during third month was not statistically significant.<sup>14</sup>

In our study, after analysis of all finding and results, it is evident that outcome of surgical management is better as compared to medical management.

## CONCLUSION

In this study, 126 patients presenting with symptoms of OME in the outpatient Department of Otorhinolaryngology, Regional Institute of Medical Sciences, Imphal, Manipal, India were included in the study. We divided them randomly into 63 cases each in medical and surgical group. After statistical analysis, we conclude that the mean age of study subjects is  $8.71 \pm 2.2$  years in the group receiving medical therapy and  $8.5 \pm 2.4$  years in the surgical therapy. Main complain are decreased hearing in 100% patients followed by aural fullness, earache and tinnitus. Most of patients gave the history of nasal allergy, history of upper respiratory infections. They also gave the history of parental smoking. In pure-tone audiometry, we found that mean AB gap was  $27 \pm 4.6$  and  $28.5 \pm 5.9$  dB in medical and surgical arm preintervention, respectively. On follow-up at 1 month after intervention in both the group we found improvement in AB gap with mean gap of  $18 \pm 2.7$  dB and  $15 \pm 4.2$  dB in medical and surgical groups, respectively, and it is statistically significant ( $p < 0.05$ ). Similarly, at 3 months after intervention in both groups, mean AB gap was  $16 \pm 2.5$  and  $9.04 \pm 2.4$  dB in medical and surgical groups, respectively, which was statistically significant ( $p < 0.05$ ).

Overall, after using statistical analysis, we conclude that improvement in hearing and reduction in AB gap are more in surgical group at the third months.

## CLINICAL SIGNIFICANCE

Otitis media with effusion is a common disease of childhood and it results in decreased hearing which hampers the performance of the children and their normal growth. Thus, the study was done to compare the results of medical and surgical so that such children with OME can be treated effectively with minimum morbidity and maximum effectiveness as children are the future of the society.

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