

Oral Steroids or Watchful Waiting for Otitis Media with Effusion in Children: A Comparative Study of Hearing Outcomes

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ABSTRACT

Background: Otitis media with effusion (OME) is a common acquired hearing loss in children and can impact on language and cognitive development in most cases. Even though most cases resolve on their own, the uses of oral steroids in enhancing the clearance of effusion speed and the final outcome of hearing is still debatable.

Objective: To establish the efficacy of oral steroids as compared to watchful waiting in children with OME regarding hearing outcomes.

Methods: The comparative study was done at the Department of Otolaryngology, Services Hospital Lahore, between June 2022 and January 2023. One hundred children with the age range of 3 to 12 years diagnosed with OME were recruited and divided into two groups. Group A was treated with oral prednisolone (1mg/kg/day, faded in 2 weeks), and Group B monitored. Baseline, 4 weeks, and 12 weeks Hearing thresholds were measured by pure-tone audiometry or age-adjusted tests. Tympanometry established the presence of effusion. The main outcome was improvement in hearing (≥ 10 dB gain or normalization) and secondary outcomes were resolution of effusion and adverse effects. The analysis of data was performed with the SPSS v26.0 based on chi-square, t-test, and repeated measures ANOVA, and $p < 0.05$ was determined as significant.

Results: At the baseline, the two groups were similar. Group A also experienced an increased hearing of 12.4 ± 4.3 dB at 4 weeks as compared to 3.1 ± 2.6 dB in Group B ($p < 0.001$). By 12 weeks, the gains were still positive (14.617.2 dB vs. 8.914.8 dB; $p = 0.002$). Group A had significantly more effusion resolution at 4 and 12 weeks (70 vs. 26 and 82 vs. 58, $p = 0.001$ and 0.01, respectively). Side effects in steroid group were very mild and self limiting.

Conclusion: The short-term effects of oral steroids are much more effective than the watchful waiting in hearing improvement and clearing the effusion. Nonetheless, since spontaneous remission takes place in most children, the watchful waiting is suitable in most simple cases whereas steroids can be used on a few children who may need quick recovery.

Keywords: Otitis media with effusion, oral steroids, watchful pending, pediatric hearing loss, tympanometry.

INTRODUCTION

One of the most frequent childhood diseases is otitis media with effusion (OME) when non-purulent fluid is accumulated in the middle ear without the symptoms of acute infection¹. The prevalence of OME is estimated as high as 80 percent of children at the age of four years, highest in the age group of two to five years^{2,3}. OME is the cause of the acquired hearing loss most frequently in children and may have a serious effect on the speech, language, and cognitive development in cases of persistent or recurrent association⁴.

Treatment of OME has diverse levels of management that include conservative observation, pharmacological treatment methods or surgery. Watchful waiting is widely observed, particularly because most of the cases heal on their own within a period of three months⁵. Tympanostomy tube surgical insertion has been shown to be the most effective method of treating persistent effusion with severe hearing loss, although because of the invasiveness of the operation and complications that may affect the patient, it is not as a favourable method of initial management⁶. There are medical treatments like antihistamines, decongestants, antibiotics and corticosteroids which have been tried with varying degrees of success and none of them are recommended in all clinical guidelines⁷.

Since oral corticosteroids have potent anti-inflammatory effects, they have been suggested as treatment to decrease middle ear effusion as well as enhance hearing⁸. A number of randomized controlled trials have described short term effusion clearance and hearing threshold improvement with steroids, but their long term effect is unclear and their side effects at the

systemic level continue to be a cause of concern. Therefore, global recommendations are to use them cautiously in their daily practice, although more studies are necessary.

MATERIALS & METHODS

The comparative study was conducted in the Department of Otolaryngology, Services Hospital Lahore in collaboration with other tertiary care hospitals of Lahore, between June 2022 and January 2023. One hundred and ten children between the ages of 3 and 12 years with a diagnosis of otitis media with effusion (OME) following a clinical examination and tympanometric data were used. OME diagnosis in children who reported conducting hearing loss and middle ear effusion on pneumatic otoscopy and type B or type C tympanogram were made. Those who had acute Otitis media, had undergone prior ear surgery, craniofacial anomalies, sensorineural hearing loss, chronic suppurative otitis media or were known to have a systemic illness which contraindicated the use of steroids were excluded.

The participants were recruited through consecutive sample once the written informed verbal consent of parents or guardian was obtained. They were then divided into two groups of children. Adequate prednisolone was administered to Group A at a dosage of 1 mg/kg/day orally in a period of seven days, and was gradually tapered during the seventh week as recommended by safety in the use of steroids in children. Group B was treated in a watchful waiting mode, which consisted of frequent monitoring but not by the use of pharmacological therapy. Recommendations about standard supportive care (including avoiding allergens, concurrent infection of the upper respiratory tract, and proper follow-up visits) were available to both groups.

The baseline demographics of the individuals such as age, gender, socioeconomic status, and duration of symptoms were noted. In cooperative children at the age over five years, pure-tone audiometry was carried out, whereas, in children at the age of the

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age-appropriate conditioned audiometry, otoacoustic emission was used to determine hearing thresholds. The severity of hearing loss was grouped according to the pure-tone average (PTA) of air conduction thresholds at 0.5, 1, 2, and 4 kHz with the threshold [?]20 dB regarded as normal, 21-40 dB as mild hearing loss, 41-60 dB as moderate and >60 dB as severe hearing loss (9). Repeated Tympanometry was done at follow up to ascertain whether there was presence or disappearance of effusion.

The duration of the follow-up was 12 weeks, during which the patients were tested with regard to their hearing at baseline, 4 weeks, and 12 weeks. The major outcome was increased hearing thresholds, which was at 10 dB gain in PTA or hearing restoration of normal level. The secondary outcomes were resolution of middle ear effusion and surgical referral. All negative reactions of steroid therapy were recorded. The World Health Organization (WHO) sample size calculator was used to compute sample size with a confidence interval of 95, power of 80, expected effect size of hearing improvement with 20 recognition difference in the two groups, and a dropout rate of 10.

Statistical Analysis

The analysis of data was carried out on SPSS version 26. Demographic and clinical characteristics were summarized using descriptive statistics. Quantitative variables were the age and hearing thresholds that were measured using the mean and the standard deviation, whereas the categorical variables included gender, presence of effusion, and the extent of hearing loss, which were measured in frequencies and percentages. The analysis of the comparison between groups was done by the chi square test of categorical variables and independent sample t test of continuous variables. The analysis of variance (ANOVA) of the changes in hearing thresholds with time within and between groups was performed by using the repeat measures analysis of variance (ANOVA). The p value of below 0.05 was taken to be statistically significant.

RESULTS

The study enrolled 100 children with effusion otitis media (OME) with 50 children in each group: oral steroid group (Group A) and watchful waiting group (Group B). The general mean age of the participants was 6.8 / 2.4 years, with a small male majority (58%). The two patient groups were similar at baseline in terms of age, sex, a length of symptoms, and the severity of hearing loss (>p 0.05 all comparisons).

Table 1. Baseline demographic and clinical characteristics of children with OME (n=100).

Variable	Group A (Oral Steroids, n=50)	Group B (Watchful Waiting, n=50)	p-value
Mean age (years)	6.9 ± 2.3	6.7 ± 2.5	0.68
Gender (Male/Female)	30/20	28/22	0.68
Duration of symptoms (weeks)	8.1 ± 3.4	8.4 ± 3.7	0.72
Baseline PTA hearing threshold (dB)	34.8 ± 7.2	35.4 ± 6.9	0.64
Degree of hearing loss (%)			
Normal (≤20 dB)	0 (0%)	0 (0%)	–
Mild (21–40 dB)	40 (80%)	41 (82%)	0.79
Moderate (41–60 dB)	10 (20%)	9 (18%)	0.81
Severe (>60 dB)	0 (0%)	0 (0%)	–

Table 2. Comparison of hearing outcomes at baseline, 4 weeks, and 12 weeks.

Time point	Group A (Oral Steroids, n=50)	Group B (Watchful Waiting, n=50)	p-value
Baseline PTA (dB)	34.8 ± 7.2	35.4 ± 6.9	0.64
4 weeks PTA (dB)	22.4 ± 6.5	32.3 ± 7.1	<0.001
12 weeks PTA (dB)	20.2 ± 5.8	26.5 ± 6.3	0.002
Mean PTA improvement (dB)	14.6 ± 5.2	8.9 ± 4.8	0.002

Table 3. Tympanometric outcomes and effusion resolution.

Time point	Effusion resolved – Group A (n=50)	Effusion resolved – Group B (n=50)	p-value
4 weeks	35 (70%)	13 (26%)	<0.001
12 weeks	41 (82%)	29 (58%)	0.01

Significant oral steroid group improvement over watchful waiting group was observed on the 4-week follow-up in terms of hearing threshold. Group A had an average increase of 12.44+4.3db whereas the increase in Group B was found to be only 3.12+2.6db (p<0.001). At twelve weeks, the steroid group had had a mean improvement of 14.6+5.2dB in PTA, and the watchful waiting group recorded a mean improvement of 8.9+4.8dB (p=0.002).

The middle ear effusion was resolved (as observed by tympanometry) significantly higher in the steroid group at both follow-ups. Effusion resolution was seen at 4 weeks in 70 per cent of children in Group A and only in 26 per cent in Group B (p<0.001). The resolution rate rose to 82% in Group A and 58% in Group B by 12 weeks, and this was also a large difference (p=0.01).

Side effects of oral steroids were insignificant. Two children had transient irritability, one of them had mild gastric discomfort, which resolved without treatment. Follow-up did not show any severe systemic side effects. In general, the oral steroids proved to be much more effective in short-term hearing and effusion clearance than watchful waiting. Nonetheless, at 12 weeks, the difference between the two groups decreased, which presupposes some spontaneous recovery in the watchful waiting group.

DISCUSSION

This paper involved the comparison of the efficacy of oral steroids and watchful waiting in the treatment of otitis media with effusion (OME) in children and especially the hearing outcomes. These results showed that oral steroids caused a much higher short term recovery in hearing thresholds, and effusion resolving, than watchful waiting. During the fourth week, children who were treated with the oral prednisolone demonstrated significant improvements in pure-tone audiometry and increased clearance of effusion whereas those in the watchful waiting group only demonstrated slight improvements. At 12 weeks, the two groups demonstrated further improvements, but the oral steroid group still demonstrated better results, but the between groups difference had decreased, which is descriptive of the natural course of the OME and its propensity to spontaneous resolution^{10,11}.

The findings are in line with the past randomized controlled trials and systematic reviews that have found short term benefits of corticosteroids in OME. Williamson et al. discovered that oral steroids were able to hasten effusion clearance especially during the initial month of treatment but the efficacy declined as time progressed¹². Equally, a Cochrane review came to a conclusion; steroids might have temporary effects on middle ear functions and hearing thresholds but no long-term benefits more than 12 weeks. Our research confirms these observations and makes it clear that steroid efficacy has a time aspect¹³.

This increased frequency of effusion resolution in the group of patients using oral steroids highlights the anti-inflammatory nature of corticosteroids in attenuating mucosal edema and Eustachian tube dysfunction. Nevertheless, the partial catch-up observed in watchful waiting group at 12 weeks indicates that a large percentage of cases of OME resolve on its own, and thus supports the idea that OME in children with mild symptoms can be treated conservatively. This is in tandem with the global guidelines like the one suggested by the American Academy of Otolaryngology-Head and Neck Surgery, which advocates first line of watchful waiting in the management of uncomplicated OME, followed by pharmacologic or surgical management in persistent cases that are accompanied by serious hearing loss or developmental risk¹⁴⁻¹⁶.

A major discovery of this research was safety of short-course oral steroids in children. Side effects were minor, self limited and included irritability and stomach problems and no severe complications were reported. This contributes to the evidence that steroid treatment of a short-term nature, when done prudently, is comparatively safe in children¹⁷. However, there are still some worries about the possibility of systemic side effects especially when using repeated or extended courses, which makes it necessary to take precautions during the routine use¹⁸⁻²⁰.

The clinical implication of our research is that oral steroids can be considered in children with OME who present with a significant hearing loss and in whom a speedy improvement is preferable including those with speech delay, academic challenges or with repeated effusions. Nevertheless, watchful waiting approach can be used in otherwise asymptomatic children, based on the natural course and the willingness to prevent the unwarranted exposure to medication. Among the strengths of this study, one can distinguish a clearly defined patient population, standardized hearing tests, and the follow-up. Nonetheless, there are restrictions that need to be taken into consideration. The sample size was small, which can be a limitation to the generalizability. The post intervention period was limited to 12 weeks, and hence, there was no evaluation of long term recurrence rates, and long term hearing outcomes. Also, the research lacked a placebo sample, a factor that might have been used to further put the actual impact of steroids into perspective, over and above the natural healing. The need to use multicenter randomized controlled trials with larger cohorts and more extensive follow-ups would be justified to determine the role of corticosteroids in the management of OME in the long term.

CONCLUSION

The oral steroids have a strong short-term effect on hearing thresholds and effusion improvement among children with effusion in otitis media compared to watchful waiting. The benefits however reduce with time since in most cases spontaneous solution is realized. Oral steroids can be discussed in the context of selected children who have to improve fast, but watchful waiting is a safe and correct approach to most of them. The individualization of clinical decisions ought to weigh the possible benefits and the risks of systemic therapy.

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