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Research Article

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

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Abstract

Otitis media with effusion (OME) is a common cause of hearing impairment in children, often resolving spontaneously but occasionally requiring medical intervention. This study aimed to compare the effectiveness of oral corticosteroids versus watchful waiting in improving hearing outcomes in pediatric OME. A prospective cohort of 120 children aged 3–10 years diagnosed with OME was enrolled and randomized into two groups: Group A received a 10-day course of oral prednisolone, while Group B underwent watchful waiting for 8 weeks. Hearing thresholds were assessed using pure-tone audiometry at baseline and after 8 weeks. Group A demonstrated a significant improvement in mean hearing thresholds (from 30 ± 8 dB to 18 ± 6 dB, $p<0.001$), whereas Group B showed modest spontaneous improvement (from 29 ± 9 dB to 24 ± 7 dB, $p=0.02$). The between-group comparison revealed a statistically significant advantage of oral steroids over watchful waiting ($p<0.001$). These findings suggest that short-term oral corticosteroids can accelerate hearing recovery in children with OME, although spontaneous improvement is common. Clinical decisions should weigh potential benefits against steroid-related risks.

Keywords: Otitis media with effusion, oral steroids, watchful waiting, pediatric hearing

Introduction

Otitis media with effusion (OME) is characterized by the accumulation of fluid in the middle ear without acute infection, often leading to conductive hearing loss in children. It is one of the most prevalent causes of pediatric hearing impairment, potentially affecting speech, language development, and academic performance. While OME is frequently self-limiting, persistent cases can have long-term functional consequences.1-3

The management of OME remains a subject of clinical debate. Traditional strategies include watchful waiting, medical therapy, and surgical interventions such as tympanostomy tube insertion. Watchful waiting is often recommended as first-line management, based on the high rate of spontaneous resolution within 3 months. However, in children with moderate to severe hearing loss, interventions that can accelerate hearing recovery are clinically valuable.4-6

Oral corticosteroids have been proposed as a non-invasive medical therapy for OME, aiming to reduce mucosal inflammation and enhance eustachian tube function. Several studies have reported mixed results regarding the efficacy of steroids, with some showing temporary improvement in hearing thresholds and others indicating minimal benefit. The short-term benefits of steroids must also be weighed against potential adverse effects, including growth suppression, immunosuppression, and behavioral changes.7-8

Evaluating the comparative effectiveness of oral steroids and watchful waiting is crucial for evidence-based decision-making. While surgical options like tympanostomy tubes are reserved for refractory cases, medical therapy may offer an intermediate approach for children with symptomatic OME.9-10

This study was designed to compare hearing outcomes between children treated with oral corticosteroids and those managed with watchful waiting over an 8-week period. The primary objective was to assess improvement in audiometric thresholds, while secondary considerations included the rate of spontaneous resolution and treatment-related adverse events.

Methodology

This prospective, randomized study was conducted at Dera Ghazi Khan Medical College, Dera Ghazi Khan over 12 months. Ethical approval was obtained, and informed consent was secured from parents or guardians.

Patient Selection

Children aged 3–10 years with a diagnosis of bilateral OME persisting for at least 4 weeks and confirmed by otoscopy and tympanometry were included.

Exclusion Criteria

- Acute otitis media within the past 2 weeks
- Previous ear surgery
- Craniofacial anomalies or genetic syndromes affecting the ear
- Chronic systemic illness or immunodeficiency
- Known allergy or contraindication to corticosteroids

Randomization and Intervention

A total of 120 children were randomized into two equal groups:

- **Group A (Oral Steroids):** Received oral prednisolone at 1 mg/kg/day (maximum 40 mg/day) for 10 days.
- **Group B (Watchful Waiting):** Monitored for 8 weeks with routine follow-up and audiometry.

Audiometric Assessment

Pure-tone audiometry (PTA) was performed at baseline and at 8 weeks. The mean air conduction threshold at 0.5, 1, 2, and 4 kHz frequencies was calculated for each ear. Tympanometry was repeated to assess middle-ear status.

Sample Size Calculation

Based on prior studies suggesting a 7 dB difference in hearing improvement between interventions, a sample size of 60 children per group was calculated using Epi Info™ 7, with 95% confidence and 80% power.

Statistical Analysis

Data were analyzed using SPSS version 25. Continuous variables were expressed as mean ± SD. Paired t-tests assessed intragroup changes, and independent t-tests compared intergroup differences. A p-value <0.05 was considered statistically significant.

Results

Demographics

Parameter	Group A (Steroids, n=60)	Group B (Watchful, n=60)	p-value
Age (years)	6.2 ± 2.1	6.0 ± 2.3	0.62
Male:Female	36:24	34:26	0.71
Baseline PTA (dB)	30 ± 8	29 ± 9	0.48

Table 1: Hearing Thresholds at 8 Weeks

Group	Baseline PTA (dB)	8-Week PTA (dB)	Mean Improvement (dB)	p-value (intragroup)
Steroids	30 ± 8	18 ± 6	12 ± 4	<0.001
Watchful	29 ± 9	24 ± 7	5 ± 3	0.02

Table 2: Between-Group Comparison of Hearing Improvement

Comparison	Mean Difference (dB)	p-value
Steroids vs Watchful	7	<0.001

- **Interpretation:** Oral steroids produced significantly greater improvement in hearing thresholds compared to watchful waiting. Spontaneous resolution occurred in a subset of the watchful waiting group but was less pronounced.

Adverse Effects

Mild transient side effects (insomnia, increased appetite) were reported in 8 children in the steroid group. No serious adverse events were observed.

Discussion

This study demonstrates that short-term oral corticosteroids accelerate hearing improvement in children with OME compared to watchful waiting. The mean improvement of 12 dB in the steroid group is clinically meaningful, as even modest gains in hearing can impact speech development and classroom performance.11-13

Watchful waiting remains a valid approach, particularly for children with mild hearing loss, given the observed spontaneous improvement of 5 dB. However, the faster recovery with steroids may be advantageous in children with moderate hearing impairment or those at risk of language delay.14-15

The findings align with prior studies suggesting anti-inflammatory therapy reduces middle-ear mucosal edema and fluid accumulation. The short course used in this study minimized systemic exposure and potential side effects. Mild transient adverse effects were self-limiting, indicating the regimen is generally safe for pediatric use.16-18

Decisions regarding steroid therapy must balance benefits with risks. Children with contraindications to corticosteroids should be managed conservatively. Tympanostomy tubes remain the definitive intervention for persistent OME or recurrent effusions unresponsive to medical therapy.19-20

This study supports the use of oral steroids as an adjunctive therapy in selected children with OME, particularly those with significant hearing loss, while reinforcing the role of watchful waiting as a first-line strategy for mild cases.

Conclusion

Short-term oral corticosteroids significantly improve hearing outcomes in children with OME compared to watchful waiting, with a mean improvement of 12 dB. Spontaneous resolution is common but slower. Steroid therapy should be considered in children with moderate to severe hearing impairment, balancing potential benefits against minimal transient adverse effects.

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