

Oral Steroids vs Watchful Waiting for Otitis Media with Effusion in Children: A Randomized Controlled Trial on Hearing Outcomes

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Abstract

Otitis media with effusion remains a leading cause of transient conductive hearing loss in children, frequently influencing speech development, academic performance, and quality of life. Despite its high prevalence, optimal management remains controversial, particularly regarding the role of systemic corticosteroids compared with conservative observation. The present randomized controlled trial was designed to evaluate the efficacy of short-course oral steroids versus watchful waiting in improving hearing outcomes among pediatric patients diagnosed with otitis media with effusion. A total of 120 children aged 3–10 years were randomized into two equal groups. Group A received oral prednisolone for 7 days, while Group B underwent observation with no pharmacological intervention. Primary outcomes included improvement in pure tone audiometry thresholds and resolution of middle ear effusion confirmed by tympanometry. Secondary outcomes

included recurrence rate and adverse effects. Results demonstrated a statistically significant improvement in hearing thresholds in the steroid group compared with control ($p < 0.001$), with faster effusion resolution at 4 and 8 weeks follow-up. However, recurrence rates at 12 weeks showed no significant difference between groups. The discussion highlights that while oral steroids provide short-term auditory benefit, their long-term superiority remains limited. The findings suggest a potential role for short-term steroid therapy in selected cases with significant hearing impairment, though routine use cannot be universally recommended.

Keywords: Otitis media with effusion, oral steroids, pediatric hearing loss

Introduction

Otitis media with effusion (OME) is a prevalent pediatric middle ear disorder characterized by the accumulation of non-purulent fluid within the middle ear cavity without signs of acute infection. It represents

one of the most common causes of hearing impairment in children globally and is frequently associated with speech delay, learning difficulties, and behavioral challenges. The condition is particularly common in early childhood due to anatomical and immunological immaturity of the Eustachian tube, which predisposes to poor middle ear ventilation and fluid retention [1–3].

In recent years, the clinical burden of OME has been increasingly recognized not only as a transient otological condition but also as a contributor to long-term developmental consequences if inadequately managed. The fluctuating nature of conductive hearing loss associated with OME makes early intervention crucial in children during critical language acquisition periods. Although spontaneous resolution occurs in many cases, persistent effusion beyond three months remains a therapeutic challenge [2–4].

Management strategies for OME vary widely and include watchful waiting, medical therapy, and surgical interventions such as tympanostomy tube insertion. Watchful waiting remains the most widely recommended first-line approach in many guidelines due to the self-limiting nature of the disease. However, persistent cases often prompt consideration of pharmacological interventions, including systemic or intranasal corticosteroids, antihistamines, and antibiotics, despite variable evidence supporting their efficacy [3–6].

Systemic corticosteroids have been hypothesized to reduce middle ear inflammation, enhance Eustachian tube function, and promote effusion clearance. However, their use remains controversial due to concerns regarding recurrence after discontinuation and potential adverse effects in pediatric populations. Recent studies have suggested short-term improvement in hearing thresholds with steroid use, although long-term benefits remain uncertain [5–8].

The rising global emphasis on evidence-based pediatric otolaryngology has prompted renewed interest in comparative clinical trials assessing pharmacological versus conservative management of OME. Contemporary research highlights the need for well-structured randomized controlled trials to define the true clinical benefit of systemic steroids in children with effusion-related hearing loss [6–9].

In this context, the present study was designed to evaluate the effectiveness of oral corticosteroids compared with watchful waiting in improving auditory outcomes in children diagnosed with OME. The study further aims to assess effusion resolution rates, recurrence patterns, and safety profile of steroid therapy in a controlled clinical setting [7–10].

Methodology

This randomized controlled trial was conducted on pediatric patients diagnosed with otitis media with effusion presenting at Shalamar Institute of Health Sciences to a tertiary care otolaryngology unit. The study population included children aged 3 to 10 years with clinically and audiotologically confirmed unilateral or bilateral OME persisting for at least 6 weeks. Ethical approval was obtained from the institutional review board, and verbal informed consent was obtained from parents or legal guardians prior to enrollment.

A total sample size of 120 participants was calculated using Epi Info software based on an expected 20% difference in hearing improvement between groups, with 80% power and 95% confidence interval. The participants were randomly allocated into two groups using a computer-generated randomization sequence. Group A consisted of 60 children receiving oral prednisolone at a dose of 1 mg/kg/day for 7 days followed by tapering over the next 3 days. Group B included 60 children managed with watchful

waiting and no pharmacological intervention except routine follow-up.

Inclusion criteria comprised children with type B tympanogram findings, conductive hearing loss between 20–40 dB on pure tone audiometry, and absence of acute infection or structural ear anomalies. Exclusion criteria included prior ear surgery, craniofacial abnormalities, immunodeficiency disorders, recent steroid use within 3 months, and chronic allergic rhinitis requiring continuous medication.

Baseline assessment included demographic data, clinical history, otoscopic examination, pure tone audiometry, and tympanometry. Follow-up evaluations were conducted at 4

weeks, 8 weeks, and 12 weeks post-intervention. Primary outcome measures included change in hearing threshold levels and resolution of effusion on tympanometry. Secondary outcomes included recurrence of effusion and any adverse drug reactions.

Data analysis was performed using statistical software. Continuous variables were expressed as mean $\pm$ standard deviation, while categorical variables were expressed as percentages. Independent t-test was applied for comparison of means, and chi-square test was used for categorical variables. A p-value of less than 0.05 was considered statistically significant

Results

Table 1: Baseline demographic and clinical characteristics

Variable	Steroid Group (n=60)	Control Group (n=60)	p-value
Mean age (years)	6.2 $\pm$ 2.1	6.0 $\pm$ 2.3	0.64
Male (%)	58%	55%	0.72
Bilateral OME (%)	63%	60%	0.81
Baseline hearing loss (dB)	31.4 $\pm$ 5.2	30.9 $\pm$ 5.6	0.58
Duration of symptoms (weeks)	8.1 $\pm$ 2.4	8.3 $\pm$ 2.6	0.67

The baseline characteristics were comparable between both groups with no statistically significant differences, indicating proper randomization and homogeneity of study population.

Table 2: Primary outcome – hearing improvement and effusion resolution

Outcome	Steroid Group	Control Group	p-value
Hearing threshold at 4 weeks (dB)	22.1 $\pm$ 4.3	28.5 $\pm$ 5.1	<0.001
Hearing threshold at 8 weeks (dB)	18.4 $\pm$ 3.8	25.6 $\pm$ 4.7	<0.001
Effusion resolution at 4 weeks (%)	68%	35%	<0.001

Outcome	Steroid Group	Control Group	p-value
Effusion resolution at 8 weeks (%)	85%	58%	0.002

Significant improvement in hearing thresholds and effusion clearance was observed in the steroid group, particularly in early follow-up periods.

Table 3: Secondary outcomes and safety profile

Outcome	Steroid Group	Control Group	p-value
Recurrence at 12 weeks (%)	18%	22%	0.54
Need for surgical intervention (%)	10%	18%	0.18
Behavioral side effects (%)	12%	3%	0.04
Overall complication rate (%)	15%	6%	0.03

Although recurrence rates were comparable, steroid-associated mild behavioral side effects were more frequently observed.

The steroid group demonstrated significantly faster improvement in hearing thresholds and effusion clearance compared to watchful waiting. However, long-term recurrence rates did not differ significantly, suggesting limited sustained benefit beyond the early treatment phase.

Discussion

The findings of the present randomized controlled trial demonstrate that short-course oral corticosteroid therapy provides significant short-term improvement in hearing outcomes among children with otitis media with effusion. The observed reduction in conductive hearing thresholds at 4 and 8 weeks supports the anti-inflammatory

mechanism of steroids in enhancing middle ear ventilation and fluid clearance [11–12].

The rapid resolution of effusion in the steroid group aligns with recent clinical observations suggesting that corticosteroids may temporarily reduce mucosal edema within the Eustachian tube, thereby improving aeration of the middle ear space. However, the absence of sustained long-term benefit at 12 weeks indicates that the underlying pathophysiological predisposition remains unaltered [12–13].

Comparative evidence from recent pediatric otolaryngology studies indicates similar short-term efficacy of systemic steroids but highlights inconsistent long-term outcomes. This supports the hypothesis that OME is a multifactorial condition where inflammation is only one contributing component [13–14].

The recurrence patterns observed in the current study suggest that while pharmacological intervention can accelerate recovery, it does not significantly modify disease recurrence trajectory. This finding is consistent with recent multicenter trials evaluating conservative versus medical management strategies [14–15].

The safety profile observed indicates a slightly increased incidence of behavioral changes in the steroid group, which is consistent with known pediatric corticosteroid effects. Although these effects were mild and self-limiting, they remain clinically relevant when considering routine use in children [15–16].

From a clinical perspective, the results suggest that oral steroids may be selectively beneficial in cases where rapid hearing improvement is required, such as children with significant speech delay or learning difficulties. However, routine administration for all OME cases cannot be justified given the lack of long-term superiority [16–18].

Overall, the findings reinforce the importance of individualized treatment strategies in pediatric OME. Watchful waiting remains a valid approach for most cases, while corticosteroids may serve as a targeted short-term intervention in carefully selected patients [18–20].

Conclusion

Oral corticosteroids demonstrate significant short-term improvement in hearing outcomes and effusion resolution in children with otitis media with effusion. Long-term recurrence rates remain unaffected, indicating limited sustained therapeutic advantage. Selective use of steroids may be justified in specific clinical scenarios, while watchful waiting remains the standard first-line approach.

References

1. Rosenfeld RM, et al. Otitis media with effusion clinical practice guidelines.
2. Kujala T, et al. Pediatric middle ear effusion and hearing outcomes.
3. Browning GG, et al. Management of otitis media in children.
4. Lieberthal AS, et al. Otitis media diagnosis and treatment update.
5. Mandel EM, et al. Corticosteroids in middle ear disease.
6. Takata GS, et al. Systematic review of otitis media interventions.
7. Simpson SA, et al. Medical management of otitis media with effusion.
8. Williamson IG, et al. Steroid therapy in pediatric ear disease.
9. van Zon A, et al. Otitis media treatment strategies review.
10. Flynn T, et al. Hearing loss in children with effusion.
11. Shekelle P, et al. Evidence-based management of OME.
12. Caye-Thomasen P, et al. Middle ear pathophysiology.
13. Paradise JL, et al. Natural history of otitis media with effusion.
14. Williamson I, et al. Clinical trials in pediatric otitis media.
15. Stool SE, et al. Pediatric otolaryngology outcomes.
16. Rosenfeld RM, et al. Updated OME guideline evidence.
17. Casselbrant ML, et al. Middle ear disease in children.
18. Gates GA, et al. Tympanostomy and medical alternatives.
19. Lous J, et al. Systematic review of OME treatments.
20. Browning GG, et al. Long-term outcomes in pediatric OME.