

A Prospective Randomized Single-Blinded Study Comparing Clinical and Audiological Outcomes of Oral Steroids, Intranasal Steroids, and Saline in Patients with Otitis Media with Effusion.

Dr Monika Deswal, Dr Meenakshi Rana, Dr Ashima Rana

Department Of Otorhinolaryngology- Head and Neck Surgery
Rajshree Medical Research Institute & Hospital

Abstract:

Background: Otitis media with effusion is one of the most common causes of hearing loss, not only in children but can also be seen in adults. It is a condition in which fluid collects in the middle ear without signs of an acute ear infection. Unlike acute otitis media, it does not cause severe pain or fever. Diagnosis is made through ear examination using an otoscope and hearing tests. Most cases resolve on their own, but persistent fluid may require long treatment and can lead to significant auditory deficits and delayed language development, particularly in children¹. While various medical therapies are employed to facilitate effusion clearance, the comparative effectiveness of systemic versus topical treatments remains a subject of clinical interest.

Objective- To compare the clinical and Audiological effectiveness of oral steroid with nasal steroids and normal saline in improving hearing in cases of unresolved otitis media presenting with middle ear effusion.

Method – A prospective randomized single blinded study was conducted over a period of 2 years involving 90 OPD patients diagnosed with unresolved otitis media based on clinical findings and audiological evaluation. Patients were randomly categorized into three groups- Group A received a short course of oral steroids, Group B received Nasal steroid sprays and Group C received Normal saline nasal spray for 10 days. Outcomes were measured based on Symptom improvement, otoscopic findings, pure tone audiometry and impedance audiometry.

Results- Patients who were treated with oral steroids demonstrated a statistical improvement in hearing thresholds and tympanometry patterns compared to the other groups. Resolution of effusion and symptomatic relief were also more pronounced in patients on oral steroids compared to Intranasal steroid therapy which yielded moderate benefits while normal saline showed limited efficacy.

Conclusion- Oral Corticosteroids play a pivotal role in the medical management of unresolved OME by reducing inflammation and also help in clearing the fluid from middle ear. They decrease swelling of the mucosal lining of the eustachian tube thereby showing superior clinical and audiological outcomes compared to nasal steroids and saline. While intranasal therapies may have an adjunctive or preventive value, systemic steroid therapy remains the most effective option for rapid and substantial improvement in hearing in selected cases. Early intervention with oral steroids may help reduce the need for surgical management and improve quality of life.

Date of Submission: 15-09-2026

Date of Acceptance: 27-09-2026

I. Introduction

Otitis Media with effusion is also referred to as serous otitis media or Middle ear effusion (MEE) is a common otological condition characterized by the presence of non-purulent fluid within the middle ear cavity without signs and symptoms of acute infection. It represents a significant cause of conductive hearing impairment, particularly in children and constitutes a major public health concern because of its impact on speech development, language development and quality of life. In adults, OME may signify underlying pathology of the Eustachian tube or nasopharynx and therefore requires a need for careful evaluation.

Normal middle ear physiology depends on effective Eustachian tube function, which maintains middle ear aeration, equalizes pressure with the ambient atmosphere, protects the middle ear from nasopharyngeal secretions and sound pressure, and facilitates clearance of secretions. Disruption of these functions, most commonly due to Eustachian tube dysfunction, results in negative middle ear pressure and transudation of fluid into the middle ear space, leading to effusion formation. Data from various studies have highlighted Allergy and upper respiratory tract infections resulting in eustachian tube dysfunction to be the most common cause, however other factors like ciliary dysfunction, proliferation of fluid producing goblet cells, and residual bacterial antigens and biofilms have also been reported³.

OME is often asymptomatic, precise global incidence and prevalence rates are challenging to establish; however, large cohort studies indicate that by the age of 10, approximately 80 % of children have experienced at least one episode of OME, with peak occurrence between 2 and 5 years of age³. While specific breakdowns for OME alone are not universally reported in large burden studies, the overall age-standardized prevalence of otitis media in children was estimated at approximately 14,775 cases per 100,000 population in 2021, with tens of millions of prevalent cases worldwide, and significant disability-adjusted life years (DALYs), especially in South Asia and Sub-Saharan Africa⁴. OME is typically a paediatric disease due to anatomical and immunological factors; however, adult-onset OME also contributes to the disease burden, with epidemiological studies reporting prevalence rates of around 3 % in adult clinical series⁵. Also, in a study conducted in South India, Persistent or unresolved otitis media has been reported with a prevalence of 19.2% with male preponderance⁶.

Clinically, OME is typically asymptomatic with respect to pain and systemic illness, distinguishing it from acute otitis media. The predominant manifestation is conductive hearing loss, which may be subtle and fluctuates in severity. In children, this hearing deficit can present indirectly through inattentiveness, delayed speech and language development, behavioural problems, or poor scholastic performance. Adults may complain of aural fullness, hearing impairment, tinnitus, or a sensation of ear blockage.

Diagnosis of middle ear effusion is primarily clinical, supported by otoscopic findings such as a dull or retracted tympanic membrane, impaired mobility on pneumatic otoscopy, visible air-fluid levels, or amber discoloration of the tympanic membrane. Audiological assessment often reveals a mild to moderate conductive hearing loss. Tympanometry serves as an objective and sensitive tool for confirming the presence of effusion, typically demonstrating a flat (Type B) tympanogram. In adults, particularly with unilateral effusion, further evaluation including nasopharyngeal examination is essential to exclude neoplastic causes.

The natural history of middle ear effusion is often self-limiting, with spontaneous resolution occurring in a majority of cases within weeks to months. Nevertheless, persistence of effusion can lead to complications such as chronic hearing loss, tympanic membrane retraction, atelectasis, cholesteatoma formation, and ossicular chain erosion. Consequently, understanding the pathophysiology, clinical implications, and appropriate management strategies of OME is crucial for otolaryngologists and primary care physicians alike.

Several drugs have been evaluated in the management of OME, including antibiotics, antihistamines, decongestants, mucolytics, and steroids. However, robust evidence has demonstrated limited or no long-term benefit of most medical therapies in altering the natural history of the disease so most of the time spontaneous regression with a wait and watch policy is advocated. However, in this fast-paced world with advent of newer technologies patient prefer an instant relief and spontaneous regression is the last resort. And it was also noted when spontaneous regression didn't occur some patients are offered myringotomy with insertion of ventilation tubes through the tympanic membrane.

Steroids when used in middle ear effusion exert beneficial effect because of its anti-inflammatory properties thereby reducing the inflammatory cascade by stabilising membrane phospholipid breakdown, thus preventing the formation of arachidonic acid and, in turn, inflammatory mediators^{7,8}. In addition, steroids may have an effect on OME by shrinking peri tubal lymphoid tissue, promoting secretion of Eustachian tube surfactant, and reducing the viscosity of middle ear fluid⁷ and can thereby obviate the need for a surgical intervention. Topical steroid applied through nose as nasal sprays primarily act on the nasal mucosa and nasopharynx with minimal penetration to the eustachian tube and would not be expected to reach the middle ear. However systemic steroids are absorbed reaching the middle ear mucosa via the bloodstream and also have shown to modulate OME in animal models⁸. Evidence from in vitro and animal models suggests that steroids reduce effusions and middle ear pressure⁸. Various mechanisms have been proposed for a role for steroids in resolving middle ear effusions, including (a) reducing arachidonic acid and associated inflammatory mediators, (b) shrinking peri-eustachian tube lymphoid tissue, (c) enhancing secretion of Eustachian tube surfactant with a resultant improvement in tubal function, and (d) reducing middle ear fluid viscosity by its action on mucoproteins^{7,8}.

Moreover, data also suggested that short courses of oral steroids such as prednisolone do not have lasting negative effects on bone metabolism, bone density, adrenal gland function or weight or height, even if used on several occasions over the course of a year⁹.

We conducted a study in patients with persistent otitis media with effusion even after 4 weeks of treatment for otitis media with hearing loss or aural fullness.

The aim was to compare the clinical effectiveness of oral steroid with nasal steroids and normal saline in improving hearing in of cases of unresolved otitis media presenting with effusions. Also assessing the effects of

oral steroids, nasal steroid and normal saline on middle ear effusion as assessed by otoscopy, Pure tone audiometry and impedance audiometry.

II. METHODOLOGY

90 patients with persistent otitis media with effusion over a period of 2 years from October 2023 to 2025 were included in the study.

Inclusion criteria

1. Individuals in age group of 12-50 years who presented to OPD with Acute otitis media and in spite of treatment with prophylactic antibiotics, decongestants, antihistamines and analgesics persisted with symptoms of hearing loss even after treatment for 4 weeks.
2. Otoscopic findings showed of presence of fluid in middle ear.
3. Audiometry confirmed a hearing loss of more than 20 dbs.
4. Impedance Audiometry showed B type curve.

Exclusion criteria

1. Chronic comorbid conditions (e.g.- Diabetes mellitus, renal failure, heart failure, tuberculosis, autoimmune diseases) were excluded from the study.
2. Patients with perforation in tympanic membrane or with ventilation tubes were also excluded.
3. Congenital malformation - Down syndrome, cleft palate was also excluded.
4. Patients having sensorineural hearing loss were also excluded from the study.

Diagnostic workup of all patients was done a complete history, clinical examination and audiometry assessment (PTA and Impedance) was done. All cases who presented with acute otitis media were given prophylactic antibiotics, antihistamines, decongestants and analgesics. Patients were then reviewed in OPD after 4 weeks. Even after treatment for 4 weeks when patients stilled presented to OPD with hearing loss and on otoscopy retraction of TM or effusion in middle ear was seen such patients were then subjected either to oral steroid, nasal steroid sprays or normal saline spray. Otoscopic findings were recorded, a pure tone audiometry to diagnose the degree of hearing loss and impedance audiometry using low frequency probe tone of 226 Hz was done.

Patients were randomly divided into three equal groups

Group A- received methylprednisolone 8 mg for 5 days and then tapered over next 5 days.

Group B patients received fluticasone nasal spray twice daily for 10days.

Group C patients received normal saline nasal sprays for 10 days

All patients were evaluated on 0, 5, 10 days. At follow up visits, subjective improvement in symptoms, Otoscopic examination findings with pure tone audiometry and impedance audiometry was done before starting the steroids and after 10 days when symptoms subsided completely.

TABLE 1 BASELINE CLINICAL CHARACTERISTICS

PARAMETER	GROUP A	GROUP B	GROUP C	P VALUE
Number of patients (n)	30	30	30	
Laterality (unilateral/Bilateral)	12/18	11/19	13/17	0.87
Associated Allergic rhinitis (%)	18 (60%)	19 (63%)	17(57%)	0.93
Previous URTI (%)	21 (70%)	22(73%)	20(67%)	0.88
Baseline Aural Fullness (%)	24(80%)	23(77%)	25(83%)	0.86
Baseline hearing loss Complaint (%)	26 (87%)	25(83%)	27(90%)	0.79

TABLE 2 BASELINE OTOSCOPIC AND TYMPANOMETRY FINDINGS

FINDING	GROUP A	GROUP B	GROUP C	P VALUE
Retracted TM (%)	22 (73%)	21 (70%)	23 (77%)	0.83
Dull TM (%)	25 (83%)	24 (80%)	26 (87%)	0.78
Visible Air fluid level (%)	14 (47%)	15 (50%)	13 (43%)	0.89
Type B tympanogram %	21 (70%)	20 (67%)	22(73%)	0.88
Type C tympanogram	9 (30%)	10 (33%)	8 (27%)	0.88

Mean middle Ear pressure (daPa ± SD)	-185±40	-178±45	-190±38	0.67
--------------------------------------	---------	---------	---------	------

TABLE 3 BASELINE PURE TONE AUDIOMETRY FINDINGS

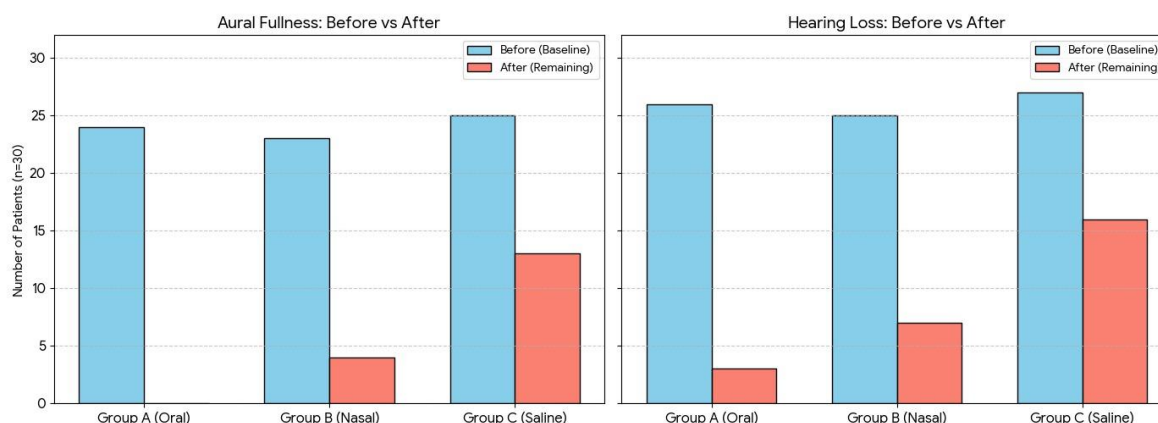
Audiometric Parameter	Group A	Group B	Group C	P value
Mean air conduction threshold (dB HL)	34.2±6.5	33.8±6.2	35.1±6.8	0.74
Mean bone conduction (dB HL)	15.6±3.8	15.9±4.0	16.1±3.9	0.81
Mean air bone gap (dB)	18.6±4.2	18.1±4.0	19.0±4.5	0.69
Mild CHL (%)	18(60%)	17(57%)	16 (53%)	0.85
Moderate CHL (%)	12 (40%)	13(43%)	14 (47%)	0.85
Average PTA (0.5,1,2 kHz)	33.8±6.1	33.2±6.4	34.6±6.7	0.76

TABLE 4: POST TREATMENT CLINICAL OUTCOME (10 DAYS FOLLOW UP)

CLINICAL OUTCOME	GROUP A	GROUP B	GROUP C	P VALUE
Resolution of Aural fullness (%)	24 (80%)	19 (63%)	12 (40%)	<0.01
Subjective hearing improvement (%)	23 (77%)	18 (60%)	11 (37%)	<0.01
Resolution of nasal Symptoms (%)	21 (70%)	22(73%)	10 (33%)	<0.001
TM normalized on otoscopy (%)	21 (70%)	17(57%)	10 (33%)	<0.01
Persistence of effusion (%)	9 (30%)	13(43%)	20(67%)	<0.01

TABLE 6 : POST TREATMENT AUDIOMETRIC IMPROVEMENT

Clinical Symptom Counts: Before and After 10-Day Treatment (N=30 per group)



TYMpanogram OUTCOME	GROUP A	GROUP B	GROUP C	P VALUE
Mean AC improvement (dB)	12.4±3.8	9.1±3.2	4.2±2.5	<0.001
Mean AB gap reduction (dB)	9.8±3.1	7.0±2.9	3.1±2.2	<0.001
PTA improvement ≥dB (%)	21(70%)	15(50%)	6 (20%)	<0.001
Complete hearing normalization (%)	18 (60%)	13(43%)	5(17%)	<0.01

Audiometric Mean Improvements (N=30 per group)

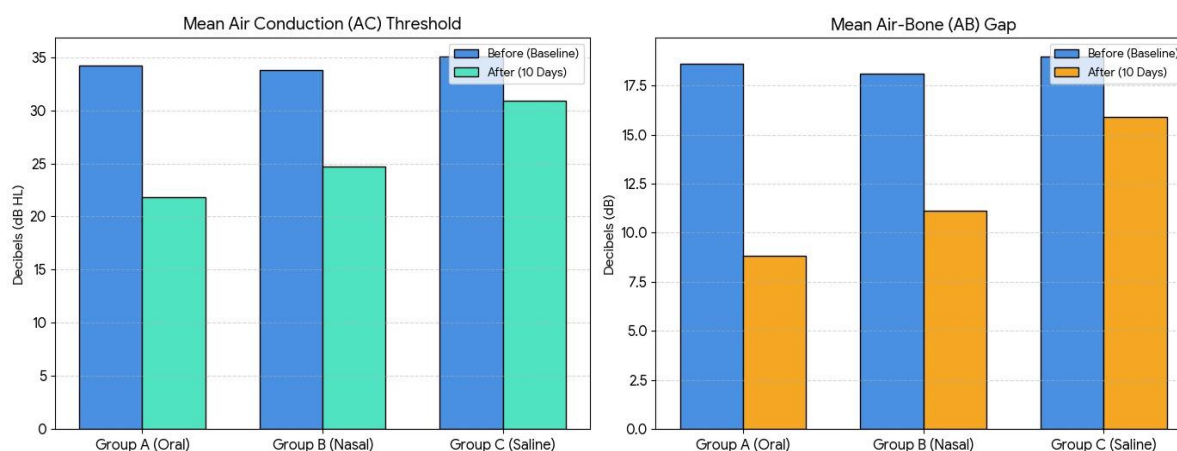


TABLE 7: INTERGROUP COMPARATIVE EFFECTIVENESS

OUTCOME MEASURE	ORAL VS NASAL	ORAL VS SALINE	NASAL VS SALINE
Symptom resolution	Significant	Highly Significant	Significant
Tympanogram normalization	Significant	Highly Significant	Significant
PTA improvement	Significant	Highly Significant	Significant
Statistical significance	P<0.05	P<0.001	P<0.05

STATISTICAL ANALYSIS

Data was analysed using SPSS version 29. Continuous variables were expressed as mean $\pm$ standard deviation and categorical variables as percentages. Inter group comparison was performed using one way ANOVA followed by post- hoc Tukey test. Paired t-test was used for intra-group comparison. Chi square test was applied for categorical data. A p value <0.05 was considered statistically significant.

III. RESULTS

A total of 90 patients with OME were enrolled and randomly allocated into three groups. Baseline Clinical audiological and tympanometry parameters were comparable across groups ($p>0.05$) with no statistically significant differences. At 10 days, group A demonstrated significantly higher rates of symptom resolution, tympanogram normalization and improvement in PTA compared to groups B & C ($p<0.05$).

IV. DISCUSSION

The present study demonstrates that oral corticosteroids provide superior short-term improvement in patients with middle ear effusion. The systemic anti-inflammatory effect likely accelerates resolution of middle ear mucosa oedema and improves eustachian tube patency.

Intranasal steroids showed moderate benefit, particularly in patients with associated allergic rhinitis, supporting the concept of unified airway inflammation. However, their effect was inferior to systemic steroids, possibly due to limited penetration into the middle ear cleft.

Normal saline nose drops, while safe and economical, showed minimal benefit when used as monotherapy. This suggests that saline irrigation alone is insufficient to reverse established middle ear pathology.

The findings of this study are consistent with previous literature demonstrating short term benefits of corticosteroid therapy, though concerns regarding recurrence and adverse effects necessitate judicious use.

V. CONCLUSION

Oral steroids provide superior short term clinical and audiometric improvement in middle ear effusion. Intranasal steroids offer a safer alternative with moderate efficacy, whereas normal saline nasal spray alone have limited therapeutic benefit.

REFERENCES

- [1]. Lehmann, KD.Charron, K.Kummer. The effects of chronic middle ear effusion on speech and language development—A Descriptive Study *Int J Pediatr Otorhinolaryngol.* 1979; 1:137-144.
- [2]. Fireman, Philip. Otitis media and eustachian tube dysfunction: Connection to allergic rhinitis. *Journal of Allergy and Clinical Immunology, Volume 99, Issue 2, s787 - s797*
- [3]. Korona-Glowniak I, Wisniewska A, Juda, M. *et al.* Bacterial aetiology of chronic otitis media with effusion in children - risk factors. *J of Otolaryngol - Head & Neck Surg* 49, 24 (2020).
- [4]. Chen R, Deng J, Sun Y, Sun D, Lu H, Jiao X, Zhu F, Lu L, Sima G. Global, regional and national burdens of otitis media in children and adolescents from 1990 to 2021 and its predictions to 2040. *Front Public Health.* 2025 Jul 3;13:1552405.
- [5]. Sogebi OA, Oyewole EA. Prevalence and Co-Morbidities of Adult-Onset Otitis Media with Effusion. *J West Afr Coll Surg.* 2022 Jan-Mar;12(1):76-82.
- [6]. Manache SK, Jangala Mm Koralla RM, Akka J. Prevalence of Otitis Media and its hearing loss in Children of South Indian population. *Int. Journal of infectious diseases.*2016; vol 45:sup 1:334.
- [7]. Vanneste P, Page C. Otitis media with effusion in children: Pathophysiology, diagnosis, and treatment. A review. *J Otol.* 2019 Jun;14(2):33-39.
- [8]. Rosenfeld RM, Mandel EM, Bluestone CD. Systemic steroids for otitis media with effusion in children. *Archives of Otolaryngology-Head & Neck Surgery* 1991;117(9):984-9.
- [9]. MacArthur C, DeGagne J, Kempton J, Trune D. Steroid Control of Acute Middle Ear Inflammation in a Mouse Model. *Arch Otolaryngol Head Neck Surg.* 2009;135:453–7.
- [10]. Harding T, Harding A. Multiple short courses of corticosteroids in children. *Aust J Gen Pract.* 2021 Mar;50(3):151-156.