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**Original Research Article** 

# **Evaluation of Risk Factors and Clinical Characteristics of Otitis Media** with Effusion in Children

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#### Abstract:

**Background:** Otitis media with effusion (OME) is a common pediatric condition characterized by non-purulent 'fluid in the middle ear, often causing hearing impairment and subtle developmental effects.

Aim: To evaluate the risk factors and clinical profile of OME among children aged 1–12 years.

**Methodology:** A hospital-based observational study was conducted on 80 children diagnosed with OME at the Department of ENT, Narayan Medical College and Hospital, Bihar, India. Data on demographics, risk factors, clinical features, audiometry, and tympanometry were collected and analyzed.

**Results:** OME was predominant among the children of 4-6 years (31.3) with a minor male bias (57.5). Low to middle socioeconomic status (85.1) and rural residence (61.3%) were widespread. The most prevalent risk factors were recurrent infections of the upper respiratory tract (60%), hypertrophy of adenoids (42.5%), passive smoking (37.5%) and attendance at daycare (31.3%). Clinically, hearing problem (70%) and ear fullness (50) were the most common. Otoscopic results revealed retracted or dull tympanic membranes in 72.5 and less mobility in 87.5. In Audiometry, mostly mild conductive hearing loss was observed (47.5%), whereas in tympanometry, Type B patterns were observed in 67.5% of cases.

**Conclusion:** OME is a multifactorial condition affecting predominantly preschool children, with significant environmental and anatomical risk factors. Early identification, preventive measures, and timely management are essential to prevent long-term auditory and developmental complications.

Keywords: Otitis Media with Effusion, Children, Risk Factors, Hearing Loss, Tympanometry, Audiometry.

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# Introduction

Otitis media with effusion is or OME, sometimes called serous or secretory otitis media, is a typical middle ear condition in children, which is of absence of non-purulent fluid behind the drum, without any indication of acute infection [1]. It ranks as one of 'the most common causes of hearing impairment among the pediatric population who are mostly affected by preschool and early-school-aged children. The disorder is mainly caused by the dysfunction of the Eustachian tube resulting to insufficient ventilation of the middle ear cavity followed by sterile effusion [2] accumulation. OME may remain asymptomatic or lead to mild symptoms, including hearing loss, fullness of the ear, and slow development of speech, and commonly remaining not noticed by the caregiver and educator. OME is very common among different populations, but it is estimated to occur in an approximation of 20-40 percent of children before school age making it a significant issue that concerns a large number of people both in the developed and developing countries.

The pathology of OME is multi-factorial, and it is an intricate complex of host, environmental, and microbial factors [3]. The most important risk factors include frequent infection of the upper respiratory tract, allergic rhinitis, sinusitis, hypertrophy of adenoid tonsils, and exposure to secondhand tobacco smoke. At the center of OME pathophysiology lies dysfunction of the eardrums of the eardrums, which affects pressure regulation and fluid clearance in the ear cavity [4]. The condition is predisposed by anatomical and physiological immaturity of the Eustachian tube in young children as it is shorter, more horizontal, and less efficient in drainage than it is in adults. In addition, genetic predisposition and clustering by family have been reported meaning that some factors are hereditary and may predispose.

Contributory factors have also been thought to be socioeconomic status, daycare attendance, supine position bottle-feeding, and seasonal factors (particularly colder months).

Clinical presentation of OME is varied and usually inconspicuous thereby making it difficult to diagnose early. Most children who develop OME remain asymptomatic and only show up in case hearing problems are realized. The conductive hearing loss is the most widespread clinical presentation and it can be both temporary and permanent in case of prolonged effusion and recurrence of the same [5]. The other signs and symptoms can be mild ear pain, ear fullness, balance problems, lack of concentration and language retardation as a result of hearing loss. The otoscopic examination usually indicates a retracted, dull, or amber colored tympanic membrane that has lesser mobility in pneumatic otoscopy [6]. Tympanometry and audiometry are vital diagnostic measures, and a type B tympanogram is typical of the middle ear effusion. In other situations, diagnostic confirmation can be done through otomicroscopy or imaging investigation, especially in situations where adenoidal hypertrophy or craniofacial defect like cleft palate is suspected as contributory 'factors.

Natural progression of OME may not be fixed; as much as most cases get cured in a few weeks to months, a proportion of children have recurrent or chronic effusions that persist beyond three months and this may necessitate medical or surgical care [7]. Chronic OME may have extended implications, especially on language, school achievement and psychosocial wellness. Timely diagnosis and treatment are therefore very important to avoid sequelae that occur in the long term. The treatment options include hyper conservative management and medical care (improving nasal decongestants, antihistamines, and corticosteroids) through surgical interventions, including myringotomy with or without the insertion of a tympanostomy tube [8] in the treatment process. Adenoidectomy also has a role to play in recurrent or refractory cases, especially where adenoidal hypertrophy plays a role in Eustachian tube obstruction.

The risk factors and clinical profile of OME in children are critical risk factors in the effective prevention, early diagnosis and treatment of the condition [9]. OME in developing nations such as India where healthcare and general awareness of hearing impairment is poor is usually underdiagnosed or poorly managed. Primary healthcare programs and school-based screening can be important in preventing the burden of the disease. The modifiable risk factors (reduction in passive smoking, breastfeeding promotion and management of allergic and infectious upper respiratory diseases) can be identified, and the incidence of OME can be reduced significantly. In addition, an in-depth knowledge of its clinical presentation would help clinicians to differentiate

OME with other forms of hearing impairment and to design proper interventions.

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The study in OME is ongoing, with 'the emphasis on the clear understanding of the molecular and immunological pathogenesis of the disease, increasing the level of diagnostic accuracy, and enhancing the approach to its management in order to reduce its recurrence and chronic effects. Since the condition has been one of the primary causes of preventable childhood hearing loss, thorough research on the epidemiology, risk factors, and clinical presentation of the disease is needed to formulate region-specific prevention and treatment strategies. In this respect, the current research will examine the risk factors that are related to otitis media with effusion and demarcate its clinical presentation in children, hence, informing the insight into its burden and helping to implement more effective social measures in the population.

## Methodology

**Study Design:** The current study was an observational study that was carried out in a hospital to assess the risk factors and clinical profile of otitis media with effusion (OME) in children. The design was to determine the demographic, environmental and clinical factors that were leading to OME and to explain audiological and tympanometric factors in the already affected pediatric population.

**Study Area:** The study was carried out in the Department of Otorhinolaryngology (ENT), Narayan Medical College and Hospital, Jamuhar, Sasaram, Bihar, India for one year.

**Study Participants:** Children attending the ENT outpatient department who were clinically diagnosed with otitis media with effusion were included in the study after obtaining informed consent from their parents or guardians.

## **Inclusion Criteria**

- Children aged between 1 and 12 years diagnosed with OME based on otoscopic and tympanometric findings.
- Children presenting with conductive hearing loss confirmed by audiometric evaluation.
- Those whose parents or guardians gave informed consent for participation in the study.

### **Exclusion Criteria**

- Children with acute otitis media, chronic suppurative otitis media, or perforated tympanic membrane.
- Children with a history of previous ear surgery, craniofacial abnormalities, or cleft palate.
- Children with neurological disorders or sensorineural hearing loss.

**Sample Size:** A total of 80 children diagnosed with OME were included in the study based on clinical

evaluation and diagnostic confirmation. The sample size was determined considering the availability of patients during the study period and the inclusion criteria.

**Procedure:** Each participant underwent a detailed clinical history, otoscopic examination, and audiological assessment.

Data on demographic factors, risk determinants such as recurrent upper respiratory tract infections, passive smoking exposure, allergy, adenoid hypertrophy, socioeconomic status, and feeding patterns were recorded using a structured proforma.

A Welch Allyn portable otoscope was used for ear examination to visualize the external auditory canal and tympanic membrane for signs such as dullness, retraction, air-fluid levels, or reduced mobility suggestive of otitis media with effusion.

An Arphi audiometer was used to perform pure tone audiometry to determine the hearing thresholds of children at standard frequencies (500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz), and the severity of hearing loss was classified as mild (26–40 dB), moderate (41–55 dB), moderate to severe (56–70 dB), severe (71–90 dB), or profound (>90 dB).

A LABAT Audiolab Plus impedance audiometer was used for impedance audiometry (tympanometry) to evaluate middle ear pressure and compliance. Tympanometric results were categorized as Type A (normal), Type B (flat curve indicating effusion), or Type C (negative pressure suggesting Eustachian tube dysfunction).

Statistical Analysis: Data obtained were tabulated and analyzed in SPSS version 27.0 (IBM Corp., Chicago, USA). Continuous variables were analyzed using descriptive statistics like mean ± standard deviation (SD), whereas the frequency and percentage were used in the categorical variables. The Chisquare test was used to establish the association of different risk factors with the occurrence of OME. Independent t-tests and one-way ANOVA were used where necessary in order to assess the relationship between demographic parameters and audiological outcomes. The P-value of less than 0.05 was considered to be statistically significant.

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#### Result

Table 1 shows the demographic data of the 80 participants of the study. The age group distribution indicates that the largest group was 4-6 years (31.3), 7-9 years (25), 1-3 years (22.5) and 10-12 years (21.2). Gender wise, there was a larger percentage of the sample who were males (57.5) than the females (42.5). With respect to residence, majority of the participants lived in the countryside (61.3%), and 38.7% in urban areas. Analysis of the socioeconomic status showed that the percentage of children who belonged to low (43.8) and middle (41.3) socioeconomic groups were overwhelming with only 15% of children belonging to the high socioeconomic group only. These results indicate that younger, 'rural, and children with lower socioeconomic status were more likely to have otitis media with effusion.

Table 1: Demographic Characteristics of Study Participants (n = 80)			
Variable	Category	Number (n)	Percentage (%)
	1–3	18	22.5
Age Group (years)	4–6	25	31.3
	7–9	20	25
	10–12	17	21.2
Gender	Male	46	57.5
	Female	34	42.5
Residence	Rural	49	61.3
	Urban	31	38.7
	Low	35	43.8
Socioeconomic Status	Middle	33	41.3
	High	12	15

Table 2 shows that among the study participants, there is a distribution of various risk factors that is related to otitis media with effusion (OME). The most common risk factor recurrent upper respiratory tract infection (URTI) was found in 60 percent of the children indicating its high correlation to OME development. Hypetrophy of the adenoid glands was noted in 42.5% of individuals and this once again indicated that it also plays a contributory role in the pathology of the middle ear. Exposure to passive

smoking and bottle feeding was reported as 37.5% and 35% among children respectively indicating that environmental as well as feeding habits can affect the development of OME. Day care or other high-density settings were reported to be attended by 31.3% of the participants, which implies that they are more at risk since they are often exposed to infections. Allergy/atopy was noted in 27.5 percent of children with the family history of OME being the least identified risk factor, with 22.5 percent of the

children carrying it. On the whole, the given table emphasizes that various confounding interconnected elements, in particular, recurrent URTI and adenoid hypertrophy, play a major 'role in OME prevalence in children.

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Table 2: Distribution of Risk Factors Associated with OME				
Risk Factor	Present (n)	Percentage (%)	Absent (n)	Percentage (%)
Recurrent Upper Respiratory Tract	48	60	32	40
Infection (URTI)				
Passive Smoking Exposure	30	37.5	50	62.5
Allergy / Atopy	22	27.5	58	72.5
Adenoid Hypertrophy	34	42.5	46	57.5
<b>Bottle Feeding</b>	28	35	52	65
Family History of OME	18	22.5	62	77.5
Attendance in Daycare / Crowded	25	31.3	55	68.7
Setting				

Table 3 shows the clinical presentation and otoscopic appearance of children with otitis media with effusion (OME). The most common symptom reported was hearing difficulty where 70 percent of people complained about the symptom with 50 percent observing sensations of ear fullness or blockage. It has been observed that 18.8% of the children had speech delay or poor performance in school and this is a pointer that persistent OME may have developmental effects. The ootoscopic analysis showed that 72.5% had a dull or retracted tympanic membrane and there was an air-fluid level present in 25% of the cases. The reduced movement of the tympanic membrane was the most prevalent otoscopic observation at 87.5% of children and this indicated middle ear effusion. Of the 111 cases, bilateral involvement was seen in 57.5 and unilateral in 42.5 hence bilateral disease was found to prevail in the study population.

Table 3: Clinical Presentation and Otoscopic Findings			
Clinical Feature	Number (n)	Percentage (%)	
Hearing Difficulty	56	70	
Ear Fullness or Blockage	40	50	
Speech Delay / Poor School Performance	15	18.8	
Dull / Retracted Tympanic Membrane	58	72.5	
Air-fluid Level Visible	20	25	
Reduced Tympanic Membrane Mobility	70	87.5	
Bilateral Involvement	46	57.5	
Unilateral Involvement	34	42.5	

Table 4 shows the spread of audiometric results in children with otitis media with effusion (OME). Most of the patients (47.5) had mild hearing loss with thresholds between 26 and 40 dB, then 31.3% patients had moderate hearing loss (4155 dB). The percentage of children with moderate to severe hearing loss (12.5), severe hearing loss (6.2) and

profound hearing loss (2.5) were lower. The average hearing threshold among all the patients was given as 38.2 8.7 dB which means that most of the affected children had mild forms of auditory impairment, and severe cases of hearing loss were not very common.

Table 4: Distribution of Audiometric Findings Among OME Patients			
Degree of Hearing Loss	Hearing Threshold (dB)	Number (n)	Percentage (%)
Mild	26–40	38	47.5
Moderate	41–55	25	31.3
Moderate to Severe	56–70	10	12.5
Severe	71–90	5	6.2
Profound	>90	2	2.5
$Mean \pm SD (dB)$	_	$38.2 \pm 8.7$	_

Table 5 shows 'the pattern of distributions of tympanometric patterns among the study participants. Most children (54/80) had a Type B tympanogram, and it was reported that they had middle ear effusion.

In 16 participants (20%), Type C tympanogram, which is negative middle ear pressure and which is suggestive of Eustachian tube dysfunction was observed. Type A tympanogram, signifying normal

middle ear compliance and pressure, was only shown by a small percentage 10 children (12.5%). These results point to the finding that majority of

children in the study were having middle ear pathology with effusion being the most common abnormality.

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Table 5: Tympanometric Patterns Among Study Participants			
Tympanogram Type	Interpretation	Number (n)	Percentage (%)
Type A	Normal middle ear pressure and compliance	10	12.5
Type B	Flat curve – Suggestive of fluid in middle ear (effusion)	54	67.5
Type C	Negative pressure – Suggestive of Eustachian tube dysfunction	16	20
Total		80	100

#### **Discussion**

The current paper has assessed the demographic profiles, risk factors, clinical presentations, audiometric data, and tympanometric data of children with otitis media with effusion (OME). According to our results, OME is commonest in children aged 4-6 years (31.3%), then in children aged 7-9 years (25). This age distribution is also consistent with the previous reports about higher susceptibility to OME in preschool and early school-aged children because the Eustachian tube is immature, and the presence of upper respiratory tract infections (URTI) in this age group is high (Restuti et al., 2022; Al-Humaid and Abou-Halawa, 2014) [10-11]. The highest prevalence of OME was also observed by Humaid and Abou-Halawa (2014) among children with age 67 years (56%), which confirms the idea that younger children are at a higher risk. The minimal male dominance in our research (57.5) is also in agreement with the study of Abdullah et al. (2007) [12] that also found the prevalence rates of males as 72%, 62 and 66 respectively indicating that 'there might be a gender predisposition perhaps due to anatomy or environmental conditions. Nevertheless, Carter et al. (2016) [13] stated that the difference in prevalence rates among populations may also be caused by racial and socioeconomic disparities, which means that the dominance of males is not universal.

We have found that the sample size was representative (61.3) of children in rural settings and the sample size was dominated by the low and middle socioeconomic groups (85.1). This result corresponds to the literature, which indicates that inadequate access to medical care, overpopulation, and postponed medical treatment are strong risk factors of OME (Choffor-Nchinda et al., 2020) [14]. The higher number of children with less socioeconomic status underscores the importance of both environmental and social factors in the pathogenesis of OME, especially in the environment where there is a high rate of infection and unhealthy nutrition.

The commonest predisposing factor was recurrent URTIs (60%), then adenoid hypertrophy (42.5%), passive smoking (37.5%), bottle feeding (35%), daycare attendance (31.3 percent), allergy/atopy

(27.5 percent), and family history of OME (22.5 percent). These results are similar to Restuti et al. (2022) [10] who found URTIs in half of the affected children, and Rout et al. (2013) [15] who found adenoid hypertrophy in 45% of cases. Passive smoking and visiting daycare are the most obvious environmental risk factors and their high rates in our research are similar to those of Bamaraki et al. (2022) [16] who reported passive smoke exposure in 35% of children with OME and daycare attendance in 28% of children. These convergences support the concept of multifactorial etiology of OME in which infectious, anatomical, environmental, and familial factors interact to predispose children to middle ear effusion.

The most common symptom was clinical hearing difficulty (70%), ear fullness (50%), and speech delay or poor school performance (18.8%). These results are in line with Perez-Herrera et al. (2020) [17] who found hearing issues in 6065 percent of children with OME and emphasized the developmental implications of chronic middle ear effusion. In our study, the otoscopic study revealed dull or retracted tympanic membrane in 72.5% and air-fluid level in 25% with reduced movement of the tympanic membrane in 87.5%. Sharma et al. (2015) [18] report similar otoscopic appearances with dull/retracted tympanic membranes reported in 74 percent of the ears, which indicates that the movement and location of the tympanic membrane is more diagnostically significant than the color changes.

Audiometric examination showed that the mild hearing loss was 'the most prevalent (47.5%), with the average hearing threshold being 38.20200-8.7. There were mild levels of hearing loss (31.3%), and severe hearing loss was rare. In part, these findings are in line with those of Amiri et al. (2018) [19], who did not indicate significant differences in the prevalence of mild, moderate, and severe cases of conductive hearing loss among children, 22, 56, and 37 percent, respectively. The variation in the prevalence of mild hearing loss could be explained by the fact that the study population, age distribution, and chronicity of the disease vary. The fact that mild conductive hearing loss is the most common form of loss enables us to emphasize the significance of early

intervention in averting the impact of the loss on speech and academic achievement as we grow older.

The Type B tympanograms were found in 67.5% of children, the Type C in 20 and Type A in 12.5%. This observation compares to findings of Sanli et al. (2014) [20] that found Type B tympanograms in 66.15% and Type C in 33.85% of the children with chronic OME, and Sharma et al. (2015) [18] that found Type B tympanograms in 50.17 and Type C in 15.33%. Our Type B tympanograms were high, which validates the use of tympanometry as an objective diagnostic measure of middle ear effusion and Eustachian tube functioning.

Studies after surgery show that hearing levels tend to normalise after surgery and mild and moderate residual hearing loss is exhibited in 19-26% of cases. Whereas, the incidence of otorrhea in our study was only 10.4% during tube placement, the incidence of transient otorrhea was found in 12.5 and delayed otorrhea in 8.2 in a prior study, which shows similar rates of complication. These findings indicate that tympanostomy is a useful procedure to be used in cases of persistent OME with a rather low rate of adverse events.

Conclusively, our research supports the fact that OME is a multifactorial disorder that mainly is more common among preschool and early school-going children, and also more prevalent among boys, the rural and middle socioeconomic groups. The common risk factors that help with the disease occurrence include: URTIs, adenoid hypertrophy, passive smoking and daycare attendance. None of the assessments are conclusive, but audiometric and tympanometric evaluation dictates the existence of mild conductive hearing loss with middle ear effusion. All these findings are mostly in line with the regional and international studies where there is a great emphasis on the early detection, prevention, and timely intervention to reduce developmental and auditory sequelae as much as possible.

## Conclusion

This paper lists that otitis media with effusion (OME) is a common childhood disease, especially in children between the ages of 46 years old, with some slight male predisposition and higher rates in rural and lower socioeconomic groups. Various interlinked factors that contribute to the development of OME include repeated infections of the upper respiratory tract, adenoid hypertrophy, passive smoking, bottle feeding, attendance in daycare and allergic predisposition. The condition is mostly clinically presented as hearing loss and ear congestion, and the otoscopic observation of the condition is of retracted or dull tympanic membranes, and loss of mobility. Audiometric test indicates predominantly mild hearing loss that is conductive in nature, with middle ear effusion being established by tympanometry in the majority. These results highlight the importance of early identification, prevention, and treatment in means of avoiding auditory and developmental problems in children with the condition in the long run.

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