

Clinical Profile, Risk Factors, and Treatment Outcomes of Otitis Media with Effusion in Pediatric Patients: A Retrospective Study

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Abstract:

Background: Otitis Media with Effusion (OME) is a common pediatric condition and a leading cause of hearing impairment, potentially affecting speech, language, and cognitive development. Various environmental and clinical factors contribute to their occurrence.

Aim: To evaluate the clinical profile, risk factors, and treatment outcomes of OME among pediatric patients attending a tertiary care hospital in Bihar, India.

Methodology: This retrospective observational study was conducted in the Department of ENT, Netaji Subhas Medical College and Hospital, Amhara, Bihta, Patna, Bihar, India, over one year. Medical records of 105 pediatric patients diagnosed with OME were reviewed. Data on demographics, clinical presentation, risk factors, diagnostic findings, treatment modalities, and outcomes were analyzed using SPSS version 26.0.

Results: Among the 105 patients, 64.8% were aged 1–5 years and 59.0% were males. Hearing loss (78.1%) was the most common symptom, followed by recurrent upper respiratory tract infections (60.0%) and mouth breathing (54.3%). Major risk factors included recurrent upper respiratory tract infections (60.0%), bottle feeding (58.1%), adenoid hypertrophy (55.2%), and overcrowded living conditions (53.3%). Medical management was effective in 68.6% of cases, while 31.4% required surgical intervention. Hearing improvement was observed in 84.8% of patients.

Conclusion: OME is strongly associated with preventable risk factors. Early diagnosis and time management can improve hearing outcomes and minimize long-term complications.

Keywords: Otitis Media with Effusion, Pediatric Patients, Hearing Loss, Risk Factors, Treatment Outcomes.

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Introduction

Otitis media with effusion (OME) is one of the most common otologic conditions in children in the world and is a significant cause of hearing loss in children. OME is diagnosed by the presence of fluid in the middle ears without the typical signs and symptoms of an acute infection, including fever or hyperemia of the tympanic membrane [1]. It is often seen in infants and young children because the Eustachian tube is anatomically and functionally immature, so it makes the young child susceptible to impaired middle ear ventilation and accumulation of fluid. Epidemiological studies suggest that almost 80% of the children will have at least one OME episode by the age of 4 years, resulting in one of the most common reasons for children to attend pediatric health services and otolaryngological clinics. While OME is generally a self-limited problem, single or multiple episodes may have auditory, developmental, and psychosocial consequences [2].

Many children with OME are not symptomatic or have only vague symptoms, so this condition is often not diagnosed. OME does not have an obvious illness that is noticeable, unlike acute otitis media, and therefore is not detected and treated promptly. However, it is difficult to diagnose infants and young children because of the narrow external auditory canal, cerumen, limited cooperation, and a lack of ability to perform detailed otoscopic exams [3]. For this reason, tympanometry and audiological tests are essential complementary tests that can help in the diagnosis of middle ear effusion and evaluation of its associated hearing loss. Asymptomatic OME results in underdiagnosis, especially in the resource-limited environment where access to specialty diagnostic equipment may be limited [4].

The pathology of OME is complex and includes factors related to Eustachian tube dysfunction, upper respiratory infections, allergic inflammation, adenoid hypertrophy, environmental triggers, and host

factors. Negative pressure in the middle ear space (due to impaired Eustachian tube function) induces fluid transudation into the middle ear space. Another cause of OME may be the chronic ear effusion after resolution of an acute ear infection, which is caused by the persistent inflammation of the middle ear [5]. Risk factors for OME include factors such as low socioeconomic status, overcrowding, passive exposure to tobacco smoke, frequent URTIs, craniofacial abnormalities, day care attendance, bottle feeding, and young age. It has also been reported that incidence rates were higher in winter months when respiratory infections were more common [6].

The main clinical importance of OME is due to the effect it has on hearing. Middle ear effusion results in the lack of mobility of the tympanic membrane and affects sound transmission causing conductive hearing loss that can be mild to moderate. In early childhood when language acquisition and cognitive development is at a crucial stage, just temporary hearing loss can have a significant impact on the ability to perceive speech, language development, academic performance and social interaction [7]. Research has shown that long-term OME can be linked to delayed language development, behavioral problems, decreased attention span, and decreased educational achievement. Moreover, children with chronic OME have been shown to have sleep issues, reduced appetite, frequent ear pain, and lower quality of life for both the children and their families.

The high prevalence of OME, coupled with the costs of repeated clinical assessment and evaluation of hearing, and medical and surgical treatment, places a significant burden upon healthcare systems worldwide. Several studies have reported that the prevalence of OME varies by age, having a bimodal shape. The first and the most prominent peak is seen around the age of 2 years, and a second peak is seen around the age of 5 years [8]. In most cases there is spontaneous resolution, but in chronic OME (lasting more than three months) active management is generally necessary to avoid long-term complications. Possible complications include the development of cholesteatoma, atelectasis, permanent hearing loss, ossicular erosion and retraction of the tympanic membrane [9].

The treatment of OME depends on the length of time it lasts, the severity of the symptoms, the child's hearing ability, and any other risk factors. Many children resolve the condition on their own and treatment begins with observation and periodic check-ups. But if a case is persistent and is related to hearing loss or developmental problems, it might need medical or surgical treatment. Myringotomy and the insertion of pressure-equalizing tympanostomy tubes (PET) are considered to be the most generally accepted surgical therapy for chronic OME and are amongst the most common surgical procedures performed in children in the world. In select patients,

especially those with recurrent disease or adenoid hypertrophy [10], an adenoidectomy may be performed as well. Despite the advances in therapy, recurrence is not uncommon and identification of modifiable risk factors and outcome of therapy in particular populations is important.

Although the burden of OME is relatively low compared to India, it is still substantial especially in rural and semi-urban regions where the socioeconomic burden, overcrowding, recurrent respiratory infections, and low access to healthcare services can make the disease more likely. Unfortunately, though, there is little information on clinical characteristics, associated risk factors, and treatment outcomes of pediatric OME in Bihar. It is important to know the epidemiology and clinical features of OME in the local community to design preventive and therapeutic solutions. So, the present retrospective study was carried out in the healthcare facilities of Amhara, Bihta, Patna, Bihar, India among pediatric patients suffering from OME to find the clinical profile, associated factors and treatment outcome of OME. Results of this study should help to better recognize, act on and evidence manage OME in children.

Methodology

Study Design: This study was designed as a retrospective observational hospital-based study aimed at evaluating the clinical profile, associated risk factors, and treatment outcomes of Otitis Media with Effusion (OME) among pediatric patients. The study involved the review and analysis of medical records of children diagnosed with OME and managed at the Department of Ear, Nose, and Throat (ENT), Netaji Subhas Medical College and Hospital, Amhara, Bihta, Patna, Bihar, India.

Study Area: The study was conducted in the Department of ENT, Netaji Subhas Medical College and Hospital (NSMCH), Amhara, Bihta, Patna, Bihar, India.

Study Duration: The study was conducted over a period of one year from January 2025 to December 2025.

Sample Size: The sample size for the study was 105 pediatric patients diagnosed with Otitis Media with Effusion and fulfilling the eligibility criteria.

Study Population: The study population comprised pediatric patients aged 1-12 years who attended the ENT Outpatient Department (OPD) or were admitted to the Department of ENT at Netaji Subhas Medical College and Hospital and were diagnosed with OME during the study period.

Data Collection: Data were collected retrospectively from the medical records of pediatric patients diagnosed with Otitis Media with Effusion (OME) who attended the Department of ENT, Netaji Subhas

Medical College and Hospital, Amhara, Bihta, Patna, Bihar, India, during the study period. A structured data collection proforma was used to extract relevant information from outpatient records, inpatient files, audiological reports, and operative records. The collected variables included demographic details such as age, gender, and residence, along with clinical information including presenting complaints, duration of symptoms, laterality of disease, associated comorbidities, and risk factors such as recurrent upper respiratory tract infections, adenoid hypertrophy, allergic rhinitis, breastfeeding history, bottle feeding, daycare attendance, exposure to passive smoking, and family history of ear diseases. Diagnostic findings obtained through otoscopic examination, tympanometry, otoacoustic emission (OAE) testing, and pure tone audiometry (where applicable) were also recorded. Details regarding treatment modalities, including medical management, surgical interventions, follow-up findings, hearing outcomes, and recurrence of disease, were documented for subsequent analysis. Only records containing complete and reliable information were included in the study to ensure data accuracy and consistency.

Inclusion Criteria

1. Pediatric patients aged 1–12 years.
2. Patients diagnosed with Otitis Media with Effusion based on clinical examination and audiological assessment.
3. Patients whose medical records contained complete information regarding diagnosis, treatment, and follow-up.

Exclusion Criteria

1. Patients with acute otitis media at the time of diagnosis.
2. Patients with chronic suppurative otitis media (CSOM).
3. Patients with congenital ear anomalies.
4. Patients with craniofacial abnormalities such as cleft palate, Down syndrome, or other syndromic conditions affecting middle ear function.
5. Patients with severe neurological disorders affect hearing assessment.
6. Incomplete or missing medical records.

7. Patients with a history of ear surgery prior to the study period.

Statistical Analysis: The data collected were entered into Microsoft Excel and subsequently analyzed using the Statistical Package for Social Sciences (SPSS) software version 26.0. Descriptive statistical methods were employed to summarize the study findings, with continuous variables expressed as mean $\pm$ standard deviation (SD) and categorical variables presented as frequencies and percentages. The association between clinical characteristics, risk factors, and treatment outcomes was evaluated using the Chi-square test or Fisher's exact test, as appropriate. Continuous variables were compared using the independent sample t-test. Univariate analysis was initially performed to identify factors significantly associated with treatment outcomes and disease severity. Variables found to be statistically significant in the univariate analysis were further included in a multivariate logistic regression model to determine independent predictors of Otitis Media with Effusion and treatment success. A p-value of less than 0.05 was considered statistically significant for all analyses. The results were presented using tables, graphs, and appropriate statistical measures to facilitate interpretation and comparison with existing literature".

Result

Table 1 presents the demographic profile of the study participants. There were 105 children diagnosed with Otitis Media with Effusion (OME): 62 (59.0%) males and 43 (41.0%) females, suggesting a higher prevalence of OME in males. Most patients (68, 64.8%) were in the age group of 1–5 years, while 37 (35.2%) patients were in the age group of 6–12 years. The present finding may indicate that younger children are more vulnerable to OME, perhaps because of immaturity of the Eustachian tube of younger children. In addition, most patients were rural (67.6%) with only 32.4% urban, suggesting that children in rural areas may be more likely to be affected by OME than those in urban areas.

Table 1: Demographic Characteristics of Study Participants (N = 105)

Variable	Frequency (n)	Percentage (%)
Age 1–5 years	68	64.8
Age 6–12 years	37	35.2
Male	62	59
Female	43	41
Rural Residence	71	67.6
Urban Residence	34	32.4

Table 2 summarizes the clinical features of OME in children. Middle ear effusion is a significant cause of hearing loss as it was reported in 82 (78.1%) pa-

tients. Sixty-three (60.0%) patients had recurrent upper respiratory tract infections, mouth breathing in 57 (54.3%) patients and snoring in 49 (46.7%) pa-

tients. 46 (43.8%) children complained of ear fullness and 28 (26.7%) had speech delay. In the study population, bilateral OME occurred more than unilateral OME, with 69 (65.7%) patients having bilateral disease and 36 (34.3%) patients having unilat-

eral disease. The results presented here confirm that in children, OME is associated with hearing loss and upper airway-related symptoms are common clinical complaints.

Table 2: Clinical Profile of Pediatric Patients with OME (N = 105)

Clinical Feature	Frequency (n)	Percentage (%)
Hearing Loss	82	78.1
Ear Fullness	46	43.8
Speech Delay	28	26.7
Recurrent URTI	63	60
Mouth Breathing	57	54.3
Snoring	49	46.7
Bilateral OME	69	65.7
Unilateral OME	36	34.3

As seen in Table 3, children with OME are more likely to have risk factors than healthy children. Bottle feeding in 61 (58.1%) children, adenoid hypertrophy in 58 (55.2%) children and recurrent upper respiratory tract infections in 63 (60.0%) patients were most common. Fifty-three (53.3%) patients had overcrowded living conditions, and 42 (40.0%) patients had allergic rhinitis. Thirty-nine children

(37.1%) had been exposed to secondhand smoke, while 31 (29.5%) attended daycare. 22 (21.0%) patients had a family history of ear disease. The results showed that the environmental and host factors are significant contributors to the development of OME and that recurrent infection, feeding habits and enlarged adenoids are important.

Table 3: Risk Factors Associated with OME

Risk Factor	Present n (%)
Adenoid Hypertrophy	58 (55.2)
Allergic Rhinitis	42 (40.0)
Bottle Feeding	61 (58.1)
Passive Smoking Exposure	39 (37.1)
Daycare Attendance	31 (29.5)
Recurrent URTI	63 (60.0)
Family History of Ear Disease	22 (21.0)
Overcrowded Living Conditions	56 (53.3)

Table 4 summarizes the treatment outcomes among pediatric patients with OME. Most of the children (72, 68.6%) achieved clinical improvement after medical management alone, suggesting that conservative management was successful in most cases. In 24 (22.9%) of children with persistent middle ear effusion or hearing loss, tympanostomy tubes were required. Further, 9 (8.5%) children had an adenoidectomy with insertion of tympanostomy tubes for associated adenoid hypertrophy and recurrent disease.

The therapeutic outcomes were good, as evidenced by improvement in hearing after treatment in 89 (84.8%) patients. Persistent OME was, however, recorded in 12 (11.4%) patients and recurrence was noted in 10 (9.5%) during follow-up period. Overall, these findings suggest that many patients were responsive to treatment, but a few patients needed surgery and follow up because of the persistence or recurrence of their disease.

Table 4: Treatment Outcomes of OME (Illustrative Example, N = 105)

Treatment Outcome	Frequency (n)	Percentage (%)
Improved with Medical Management	72	68.6
Required Tympanostomy Tube Insertion	24	22.9
Required Adenoidectomy with Tube Insertion	9	8.5
Hearing Improvement After Treatment	89	84.8
Persistent OME During Follow-up	12	11.4
Recurrence of OME	10	9.5

Discussion

Otitis Media with Effusion (OME) is one of the most frequent causes of childhood hearing loss and is still a major public health problem globally. In the present retrospective study, the clinical profile, associated risk factors and clinical outcome of OME in 105 children visiting ENT Department of Netaji Subhas Medical College and Hospital, Amhara, Bihta, Patna, and Bihar has been evaluated. The findings could prove useful in understanding the epidemiological and clinical features of OME in a tertiary care center and are a part of the increasing evidence base on factors which may affect the occurrence and effectiveness of treatment for OME [11].

Most of the patients were aged between 1 and 5 years (64.8%) and 35.2% were aged between 6 and 12 years. Results were like those of earlier studies reporting that OME is a disease of early childhood, which is associated with the immaturity of the Eustachian tube. A bimodal distribution in the prevalence of OME was reported by Zielhuis et al. (1990), with the first peak at about two years of age and the second peak at about five years of age. Likewise, Cassel Brant and Mandel (2003) noted that younger children are special risk groups due to the shortness and horizontal alignment of Eustachian tubes that allow pathogens to migrate and do not promote middle ear drainage. The age-related decrease in prevalence may be due to maturation of Eustachian tube function and enhanced immune competence" [12].

This study showed a male predominance (59.0%). These findings are in line with Di Francesco et al. (2016) who reported more cases of OME in males than females. The underlying cause of the gender difference is still not understood, but some have proposed that boys might be more likely to have upper respiratory tract infections and exposure to environmental allergens in early childhood which could lead to middle ear disease. A few other studies do not report any gender association however, which means that sex differences can differ between populations [13].

The most frequent presenting symptom in this study was hearing loss (78.1%) for all children. This is a predicted finding, because a middle ear effusion decreases the mobility of the TM and will obstruct the passage of sound, thus causing conductive hearing loss. Rosenfeld et al. (2004) highlighted hearing loss as the major problem associated with OME and its implications for language acquisition, cognitive growth and educational performance. The high prevalence of bilateral OME in the current study (65.7%) further adds to the risk of clinically significant hearing deficits. Boudewyns et al. (2011) also reported similar findings, stating that OME is underdiagnosed as a cause of hearing loss in infants and young children. A relatively high proportion of patients with speech delay (26.7%) within the present study

population may be due to the chronic effects of ongoing hearing impairment in specific areas of language development.

Other symptoms such as recurrent upper respiratory tract infections (60.0%), mouth breathing (54.3 %) and snoring (46.7 %) were also commonly noticed. The results indicate that there is a close relationship between OME and upper airway disease. Other studies have shown that recurrent respiratory infections lead to Eustachian tube dysfunction and to inflammation of the middle ear space, which allows the middle ear space to fill with fluid (Daly et al., 2010). The present study has found a high prevalence of mouth breathing and snoring, which could be indicative of adenoid hypertrophy, which occurred in 55.2% of patients. Persistent middle ear disease is believed to occur due to the obstruction of nasopharyngeal opening of the Eustachian tube and due to the bacteria reservoir effect of enlarged adenoids [15].

The most common risk factors that were assessed were recurrent upper respiratory tract infections, bottle feeding, adenoid hypertrophy and overcrowding at home. Previous evidence suggests that bottle feeding is a risk factor for OME; in our sample, bottle feeding was found in 58.1% of patients. In the multivariate analysis, Di Francesco et al. (2016) found that the strongest independent predictor of OME was artificial feeding, and they concluded that breastfeeding had a protective effect for middle ear disease. The protective effects of breastfeeding could be due to the provision of maternal antibodies and better nutritional status and lower exposure to pathogens. Moreover, breastfeeding provides the position for feeding which helps to prevent milk flowing into the nasopharynx and Eustachian tube and thus helps to decrease the rate of middle ear inflammation [16].

Another notable finding of the present study is adenoid hypertrophy, which is well known as one of the most important etiological factors of pediatric OME. Coticchia et al., 2013, emphasized the role of adenoidal tissue as mechanical obstructive and as being a chronic source of bacterial colonization. The high rate of adenoid hypertrophy found in the present study justifies the importance of the adenoid surgery in selected cases of chronic OME. Similarly, the socioeconomic and environmental factors were observed as more than half of the study population (53.3%) had overcrowding. If the houses are too small, children are exposed to more respiratory infections, and the risk of repeated infections and middle ear disease is increased [17].

Allergic diseases have been on the rise as a factor in OME in recent years. In the present study, allergic rhinitis was found in 40.0% of children, which suggests that there may be a relationship between allergic airway inflammation and middle ear pathology.

Alles et al. (2001) found a high incidence of allergic disorders in children with OME and suggested that inflammation of the upper respiratory tract might be disseminated to the middle ear via the Eustachian tube. In addition, Levy et al. (2013) found that about 39% of children who need repeated tympanostomy tube placement had asthma, suggesting a unified airway in which allergic inflammation of the upper and lower respiratory tracts are related. Our prevalence of OME is similar to previous literature and indicates that allergy screening might be useful for children who have recurrent or persistent OME [18].

Environmental exposures also played a role in the occurrence of disease in the current study. Thirty-seven percent of patients reported passive smoking and 29.5% were in daycare. Environmental tobacco smoke has been shown to affect the mucociliary clearance, local immune system function and susceptibility to respiratory infections, which can predispose children to OME (Csákányi et al., 2012). Likewise, individuals who attend daycare are exposed to more viral and bacterial pathogens and have been found with a consistent link to recurrent respiratory tract infections and/or middle ear disease (Greenberg et al., 2008). While these risk factors are not the most prevalent in our study, their prevalence highlights the need for environmental changes in disease prevention [19].

With respect to treatment results, most patients (68.6%) had a positive response to medical management, 22.9% needed a tympanostomy tube placement and 8.5% needed adenoidectomy in addition to tubes. The results are consistent with current guidelines which propose a trial of observations and conservative treatment for many children with OME with surgery recommended when effusion persists, hearing loss is significant or developmental complications are present (Rosenfeld et al., 2013). The results of treatment were favorable with hearing improvement in 84.8% of patients. The same success has been reported in previous studies which compared the rate of tympanostomy tube insertion and adenoidectomy for chronic OME (collected from the literature). But one in nine children (11.4%) with the disease continued to be affected, and 9.5% of those children who had been affected had a recurrence, highlighting the chronic and recurrent nature of OME in a minority of children. In a similar study, Levy et al. 2013, found that some children had recurrent diseases even after surgical intervention, reinforcing the need for long-term follow-up and management of underlying risk factors [20].

In conclusion, the present study confirms that OME is still a frequent disease in children, mostly affecting those under the age of five, and significantly related with the presence of recurrent upper respiratory tract infections, bottle feeding, adenoid hypertrophy, allergic rhinitis and poor environmental conditions. Despite appropriate medical and surgical

treatment, most patients have good results, but persistent and recurrent disease remains a clinical challenge. Identification and prevention of risk factors can significantly diminish the burden of OME and enhance auditory and developmental outcomes of children with OME.

Conclusion

Otitis Media with Effusion (OME) remains a significant pediatric health problem, particularly among children aged 1–5 years, with hearing loss being the most common clinical manifestation. The present study demonstrated that recurrent upper respiratory tract infections, bottle feeding, adenoid hypertrophy, overcrowded living conditions, allergic rhinitis, passive smoking exposure, and daycare attendance were important risk factors associated with OME. Most children showed favorable outcomes with timely medical management, while a smaller proportion required surgical intervention, including tympanostomy tube insertion and adenoidectomy. Significant improvement in hearing status was observed following treatment, highlighting the effectiveness of appropriate therapeutic approaches. However, the persistence and recurrence of OME in some patients emphasize the need for regular follow-up and early identification of high-risk children. Overall, early diagnosis, prompt intervention, parental awareness, promotion of breastfeeding, and control of modifiable risk factors are essential for reducing the burden of OME and preventing its long-term auditory, speech, and developmental consequences in the pediatric population.

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