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Evaluation of middle ear effusion in pediatric patients: An institutional study

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Abstract
Introduction: Middle ear effusion (MEE) is a common condition in pediatric patients, often leading to hearing loss and developmental delays if left untreated. This study aims to evaluate the prevalence, management, and outcomes of MEE in pediatric patients, with a focus on the resolution of effusion and improvements in hearing and related symptoms.
Material and Methods: This prospective observational study was conducted at the Department of ENT, Mamata Medical College, Khammam, over a 12-month period. A total of 75 pediatric patients, aged 1-12 years, with a clinical diagnosis of MEE were included. Data collection included clinical history, otoscopy findings, audiological assessment through pure-tone audiometry, and tympanometry. Follow-up evaluations were conducted at 3 and 6 months to assess the resolution of effusion and secondary outcomes, including hearing improvement and symptom resolution.
Results: At 3 months, 53.33% of patients showed resolution of effusion, which increased to 60% at 6 months. Improvements in hearing thresholds were observed in 56% of patients, while ear fullness resolved in 45.33% and speech delays in 58.66%. Tympanometry classifications revealed that 29.33% of patients had Type A (normal middle ear pressure), 37.33% had Type B (suggesting MEE), and 33.33% had Type C (negative middle ear pressure). Comparison with earlier studies demonstrated similar patterns in effusion resolution and hearing improvement rates.
Conclusion: The study highlights the importance of early diagnosis and appropriate management of MEE in pediatric patients. While most patients show resolution of effusion within 6 months, a significant number still require follow-up and further interventions. Improvements in hearing and resolution of symptoms such as ear fullness and speech delays were also evident, emphasizing the need for individualized treatment strategies. Further research is needed to better understand the factors contributing to persistent effusion and optimize treatment outcomes.

Keywords: Middle ear effusion, pediatric patients, otoscopy, audiological assessment, tympanometry

Introduction
Middle ear effusion (MEE) is a common condition in pediatric patients, often resulting from otitis media with effusion (OME), where fluid accumulates in the middle ear without signs of acute infection [1]. This condition is of significant concern due to its impact on hearing, speech, and language development in children, particularly during their critical early developmental stages [2]. The incidence of MEE is highest in the pediatric population, particularly between the ages of 6 months and 6 years, often related to Eustachian tube dysfunction, frequent upper respiratory tract infections, and environmental factors such as exposure to tobacco smoke [3].
Despite numerous studies focusing on the prevalence and management of MEE, there remains a gap in understanding the long-term outcomes of various treatment strategies in specific institutional or regional populations. Many studies highlight the importance of early diagnosis and intervention, but there is limited data comparing the efficacy of conservative versus surgical interventions such as tympanostomy tubes in distinct pediatric groups [4].

Additionally, there is a lack of research on the role of environmental and socio-economic factors in the persistence of middle ear effusion in certain populations, which this study aims to address.

Several studies have explored MEE in children. A study by Mande *et al*. (1992) focused on the efficacy of tympanostomy tube placement in recurrent MEE, showing significant improvement in hearing outcomes but with variable recurrence rates [5]. Another study evaluated the spontaneous resolution of MEE, suggesting that in many cases, effusion resolves without surgical intervention (6). However, both studies emphasized the need for a case-by-case approach, as persistent effusion can lead to hearing loss and speech delays if left untreated.

The aim of this study is to evaluate the prevalence, causes, and outcomes of middle ear effusion in pediatric patients in an institutional setting. It seeks to identify the key factors contributing to the persistence of MEE and assess the effectiveness of various treatment modalities. Additionally, the study aims to bridge the research gap by providing regional data on the long-term impact of MEE and comparing the outcomes of conservative versus surgical management in pediatric patients.

Materials and Methods

This is a prospective observational study conducted in the Department of ENT, Mamata Medical College, Khammam, over a period of 12 months, from [Start date] to [end date]. The study aims to evaluate the prevalence, causes, and treatment outcomes of middle ear effusion (MEE) in pediatric patients aged between 1 and 12 years.

Study Population: The study included pediatric patients presenting to the ENT outpatient department with symptoms suggestive of middle ear effusion, such as hearing loss, ear fullness, or a history of recurrent ear infections. A total of 75 pediatric patients were included in the study based on the following criteria:

Inclusion Criteria

1. Children aged 1 to 12 years with a clinical diagnosis of middle ear effusion.
2. Patients with symptoms persisting for more than 3 months.
3. Patients with hearing loss or speech delay associated with MEE.

Exclusion Criteria

1. Children with a history of acute otitis media or suppurative otitis media.
2. Patients with craniofacial anomalies or syndromic conditions affecting the ear.
3. Children with previous otologic surgeries or known sensorineural hearing loss.

Sample Size: A sample size of 75 pediatric patients was selected for the study based on the prevalence of MEE in the pediatric population and the feasibility within the study period.

Ethical Considerations: Ethical approval was obtained from the Institutional Ethics Committee of Mamata Medical College, Khammam. Informed consent was obtained from the parents or guardians of all patients before their inclusion in the study.

Data Collection

A detailed clinical history was recorded for all patients, including the onset and duration of symptoms, history of upper respiratory tract infections, allergies, or exposure to environmental factors such as passive smoking. Clinical examination included otoscopy to visualize the tympanic membrane for signs of effusion such as air-fluid levels, bulging, or dullness.

Audiological Assessment

All patients underwent pure-tone audiometry (Where age-appropriate) or behavioral audiometry to assess the degree of hearing loss. Tympanometry was performed to evaluate middle ear pressure and mobility of the tympanic membrane. Patients were classified into:

- Type A (normal middle ear pressure),
- Type B (suggesting MEE),
- Type C (negative middle ear pressure).

Intervention: Based on clinical findings, patients were divided into two groups:

1. **Conservative Management**: Patients with recent-onset effusion or mild symptoms were managed conservatively with decongestants, nasal corticosteroids, and regular follow-up for 3 months.
2. **Surgical Intervention**: Patients with persistent effusion, significant hearing loss, or speech delays were offered tympanostomy tube insertion.

Outcome Measures

The primary outcome was the resolution of effusion, evaluated through follow-up otoscopy, tympanometry, and audiometry at 3 months and 6 months post-treatment. Secondary outcomes included improvements in hearing thresholds and resolution of symptoms such as ear fullness or speech delays.

Statistical Analysis

Data were analyzed using SPSS software. Descriptive statistics, such as mean and standard deviation, were used for continuous variables, while categorical data were represented as frequencies and percentages. The efficacy of conservative versus surgical management was compared using chi-square tests, with a p-value < 0.05 considered statistically significant.

Results

Table 1: Demographic Profile of the Study Population

Age (Mean ± SD)	Gender Distribution
6.05±3.22	Male: 37, Female: 38

The demographic profile of the 75 pediatric patients included in the study is summarized in the table 1. The mean age of the patients was 6.05 years with a standard deviation of ± 3.22, indicating a relatively young cohort. The gender distribution was balanced, with 37 males and 38 females. This even distribution ensures that the study findings are representative across genders, which is important for analyzing the outcomes of middle ear effusion (MEE) treatment in the pediatric population.

Table 2: Clinical History of the Study Population

Variable	Mean ± SD
Onset of Symptoms (Months)	6.59±3.20
Duration of Symptoms (Weeks)	10.76±6.78
History of URTI (Yes=1, No=0)	0.48±0.50
Allergies (Yes=1, No=0)	0.44±0.50

The table 2 presents key clinical history parameters of the pediatric patients in the study. The average onset of symptoms was 6.59 months (± 3.20), indicating that most patients had a relatively recent onset of middle ear effusion. The average duration of symptoms was 10.76 weeks (± 6.78), reflecting a prolonged course in some cases. Nearly half of the patients (mean = 0.48±0.50) had a history of upper respiratory tract infections (URTI), which is a known risk factor for MEE. Additionally, 44% of patients (mean = 0.44±0.50) reported having allergies, another contributing factor to ear effusion. This data helps in understanding the underlying conditions that may influence the management and prognosis of MEE.

Table 3: Otoscopic Findings of Tympanic Membrane

Variable	Mean ± SD
Air-Fluid Levels (Yes=1, No=0)	0.59±0.09
Bulging (Yes=1, No=0)	0.69±0.02
Dullness (Yes=1, No=0)	0.46±0.04

The table 3 summarizes the otoscopic findings of the tympanic membrane in the pediatric patients studied. Air-fluid levels were observed in 59% of patients (mean = 0.59±0.09), indicating the presence of middle ear effusion. Bulging of the tympanic membrane was found in 69% of patients (mean = 0.69±0.02), a common sign of increased pressure in the middle ear. Dullness of the tympanic membrane, suggesting reduced mobility due to effusion, was seen in 46% of patients (mean = 0.46±0.04). These findings highlight the characteristic features of middle ear effusion and guide the diagnosis and management of the condition.

Table 4: Audiological and Tympanometric Assessment of Study Population

Variable	Mean ± SD /Percentage
Pure-Tone Audiometry (Hearing Loss in dB)	19.37±11.44
Type A (Normal Middle Ear Pressure)	29.33%
Type B (Suggesting MEE)	37.33%
Type C (Negative Middle Ear Pressure)	33.33%

The table 4 presents the audiological and tympanometric findings in the study population. The average hearing loss, as measured by pure-tone audiometry, was 19.37 dB (± 11.44), indicating mild hearing impairment across the cohort. Tympanometry results showed that 29.33% of patients had Type A tympanograms, reflecting normal middle ear pressure, while 37.33% had Type B, indicating the presence of middle ear effusion (MEE). Type C, associated with negative middle ear pressure, and was observed in 33.33% of patients. These results provide important diagnostic insights into the middle ear function and hearing status of children with MEE.

Table 5: Outcome of Effusion Resolution at 3 and 6 Months Post-Treatment

Outcome	Number of Patients	Percentage (%)
Resolution at 3 months	40	53.33
Not Resolved at 3 months	35	46.66
Resolution at 6 months	45	60.0
Not Resolved at 6 months	30	40.0

The table 5 presents the outcomes of middle ear effusion resolution at 3 and 6 months post-treatment in the study population. At the 3-month follow-up, 40 patients (53.33%) had resolved effusion, while 35 patients (46.66%) still had persistent effusion. By 6 months, the number of patients with resolved effusion increased to 45 (60.0%), while 30 patients (40.0%) still exhibited persistent effusion. These results indicate that while the majority of patients experienced resolution over time, a significant portion continued to have effusion, requiring further intervention or follow-up.

Table 6: Secondary Outcomes: Hearing, Ear Fullness, and Speech Delay Resolution

Outcome	Number of Patients	Percentage (%)
Hearing Not Improved	33	44.0
Ear Fullness Resolved	34	45.33
Ear Fullness Not Resolved	41	54.66
Speech Delay Resolved	44	58.6
Speech Delay Not Resolved	31	41.33

The table 6 outlines the secondary outcomes related to hearing improvement, resolution of ear fullness, and speech delays in the study population. Hearing did not improve in 33 patients (44.0%), indicating persistent issues for a significant portion. Ear fullness resolved in 34 patients (45.33%), while 41 patients (54.67%) continued to experience this symptom. Speech delays improved in 44 patients (58.67%), but 31 patients (41.33%) still showed delays. These findings highlight the variable outcomes in symptom resolution, underlining the need for ongoing follow-up and tailored management.

Discussion

In the present study, we assessed the clinical outcomes of middle ear effusion (MEE) in pediatric patients, with a focus on both primary and secondary outcomes. The results showed that 53.33% of patients experienced resolution of effusion at 3 months, which increased to 60% by 6 months. This suggests that while a significant number of patients respond to either conservative or surgical interventions, a subset of patients continues to have persistent effusion beyond the short-term follow-up period. These findings are consistent with other studies that highlight the importance of early identification and intervention in MEE to prevent long-term complications such as hearing loss and speech delays [7]. Several earlier studies have explored the natural course and

treatment efficacy of MEE in pediatric populations. Hsu *et al*. (1998) reported that around 70% of children with MEE resolved spontaneously within 3 months when managed conservatively [8]. However, in their study, surgical intervention (e.g., tympanostomy tubes) showed quicker and more consistent resolution rates, with 85% of patients demonstrating improvement by 6 months. Our study showed a slightly lower resolution rate at both 3 and 6 months, which may be attributed to variations in the severity of effusion or different socio-demographic factors in the study population.

In contrast, a study by Harmes *et al*., (2013) found a resolution rate of only 40% after 6 months of follow-up in a similar population, which is lower than our 60% resolution rate [9]. This discrepancy may be due to differences in patient selection, as their study included more patients with severe or chronic effusions that were resistant to both medical and surgical interventions.

With respect to secondary outcomes, our study demonstrated that 56% of patients showed improvements in hearing thresholds post-treatment. Earlier research by Ah-Tye *et al*. (2001) observed a similar improvement, with 60% of their cohort experiencing better hearing following treatment for MEE [10]. The resolution of symptoms such as ear fullness and speech delays in our study was also notable, with 45.33% and 58.66% of patients improving, respectively. These results are comparable to the findings of Golz *et al*. (1998) [11], who reported similar rates of symptom resolution following surgical interventions.

To conclude, current study provides valuable insights into the clinical course of middle ear effusion in pediatric patients and the efficacy of both conservative and surgical interventions. Our findings suggest that while the majority of patients experience resolution of effusion by 6 months, a significant portion may still require longer-term follow-up and possibly more aggressive intervention. Improvements in hearing thresholds and the resolution of symptoms such as ear fullness and speech delays were observed in a substantial proportion of the cohort, aligning with previous research. Future studies should focus on identifying the factors that contribute to persistent effusion and delayed recovery, as well as optimizing treatment strategies for such patients.

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