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Efficacy of Medical Therapy in Patients of Otitis Media with Effusion at Ayub Teaching Hospital, Abbottabad

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ABSTRACT

Background: Otitis media with effusion (OME) is characterized by no purulent fluid accumulation in the middle ear without acute infection signs, often leading to hearing impairment and developmental delays in children. While many cases resolve spontaneously, the role of medical therapy remains controversial, with limited regional data from resource-constrained settings. **Objective**: To determine the efficacy of medical therapy in resolving middle ear effusion among pediatric patients diagnosed with OME at Ayub Teaching Hospital, Abbottabad. **Methods**: This descriptive case series included 86 children aged 1 to 15 years with OME confirmed by Type B tympanogram, treated with a ten-day regimen of oral amoxicillin, nasal decongestants, antihistamines, and mucolytics. Exclusion criteria included tympanic membrane perforation, cholesteatoma, or anatomic anomalies. Tympanometry was repeated after three months to assess resolution. Data were analyzed using SPSS v25, employing chi-square tests for associations, with $p<0.05$ considered significant. **Results**: Of 86 patients, 72.09% demonstrated resolution of middle ear effusion at three months. Efficacy was slightly higher in older children and females but without significant associations for age ($p=0.511$), gender ($p=0.115$), or symptom duration ($p=0.499$). **Conclusion**: Medical therapy achieved resolution of OME in a substantial proportion of cases, suggesting potential utility where surgical options are limited; however, further controlled trials are necessary to distinguish therapeutic effects from spontaneous resolution.

Keywords: Otitis Media with Effusion; Medical Therapy; Pediatric Otolaryngology; Tympanometry; Antibiotics; Pakistan

INTRODUCTION

Otitis media with effusion (OME) is characterized by the presence of nonpurulent fluid in the middle ear cavity without acute signs of infection, such as pain, fever, or irritability, and is commonly referred to as serous otitis media, glue ear, or secretory otitis media (1). OME frequently follows episodes of acute otitis media (AOM) but can also develop independently due to factors such as Eustachian tube dysfunction, allergies, or barotrauma (2). Globally, OME is recognized as one of the most prevalent chronic otological conditions in childhood, with epidemiological studies indicating that up to 80% of children experience at least one episode before the age of ten, and a significant proportion may have persistent effusion beyond three months, potentially impairing hearing and speech development (3,4). The condition disproportionately affects children between six months and three years of age and exhibits a bimodal distribution, peaking at two and five years, and is often observed more frequently during winter months, with higher rates reported in boys than girls (5,6).

Although spontaneous resolution of middle ear effusion occurs in many cases, persistent OME carries significant implications for speech, language acquisition, cognitive development, and quality of life, particularly in young children whose auditory input is critical for linguistic and social development (7,8). Diagnostic challenges exist because OME may be asymptomatic, with many cases detected incidentally during routine examinations or evaluations for hearing loss, underlining the necessity of adjunctive diagnostic tools like tympanometry, which can objectively assess middle ear status and fluid presence (9,10). Tympanometry findings, particularly a type B flat curve with normal canal volume, have been accepted as a reliable indicator of middle ear effusion and are commonly employed in both clinical practice and research settings (11,12). Despite advances in diagnostic techniques, management of OME remains contentious, with various pharmacologic and surgical interventions debated in the literature. International consensus guidelines, including those from the International Federation of Otorhinolaryngological Societies, generally advise against routine pharmacologic treatments, such as antibiotics, corticosteroids, decongestants, antihistamines, and mucolytics, citing limited evidence of long-term efficacy and potential adverse effects (13,14). Nevertheless, numerous clinicians continue to prescribe medical therapy, often driven by concerns over parental anxiety, risk of progression to AOM, or healthcare system constraints, highlighting a disconnect between guidelines and real-world practice (15,16). In the context of developing countries, where surgical interventions like tympanostomy tube placement may be less accessible due to cost, infrastructure limitations, or cultural factors, medical therapy remains an appealing first-line option despite international recommendations to the contrary (17). Studies assessing the

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effectiveness of medical management for OME have reported varied outcomes, with some investigations demonstrating modest short-term benefits in resolving effusion, while others indicate negligible improvements compared to observation alone (18,19). For instance, a recent Cochrane review analyzing multiple trials found no significant long-term benefits of antibiotics in reducing hearing loss or preventing surgical intervention in OME patients, while a separate investigation reported a resolution rate of approximately 66.2% with medical management (20,21). Given the discrepancies in international guidelines, regional practice patterns, and the scarcity of data specific to the Pakistani population, it becomes imperative to evaluate the effectiveness of medical therapy in children with OME in local settings.

Recognizing the significant burden of untreated OME on childhood development and the persistent practice of medical therapy in many clinical settings, this study aims to determine the efficacy of a medical treatment regimen—including amoxicillin, decongestants, antihistamines, and mucolytics—in resolving middle ear effusion in children aged 1 to 15 years diagnosed with OME at Ayub Teaching Hospital, Abbottabad. This investigation seeks to address the existing knowledge gap regarding medical management outcomes for OME within this regional context and to contribute evidence that may inform local clinical decision-making and health policy. The primary research question posed is whether medical therapy leads to resolution of middle ear effusion, as evidenced by normalization of tympanometry findings, in pediatric patients with OME within a three-month follow-up period.

MATERIAL AND METHODS

This descriptive case series was conducted to investigate the efficacy of medical therapy in children diagnosed with otitis media with effusion (OME), aiming to provide region-specific evidence for clinical decision-making in a setting where surgical interventions may not always be feasible due to resource constraints. The study was carried out in the Department of Otorhinolaryngology at Ayub Teaching Hospital, Abbottabad, Pakistan, between 1st November 2024 and 31st January 2025, enrolling patients consecutively during this period to capture a representative clinical spectrum of OME cases presenting during the winter season, when the incidence of upper respiratory infections and middle ear pathology typically increases (1).Eligible participants included children aged one to fifteen years of either sex who presented with symptoms and signs suggestive of OME persisting for more than two weeks, confirmed by diagnostic tympanometry showing a Type B curve with normal canal volume, indicating the presence of middle ear fluid. Exclusion criteria comprised patients with active ear discharge, evidence of tympanic membrane perforation, cholesteatoma, septal deviations, nasal polyps, anatomic anomalies such as cleft palate, or a history of prior ear surgery, as these conditions could confound both the etiology and response to medical therapy for OME. Participants were selected through non-probability consecutive sampling, whereby every eligible patient presenting during the study period was invited to participate, minimizing selection bias and ensuring that the sample reflected the routine clinical population.

Informed verbal consent was obtained from the parents or legal guardians of all enrolled children after explaining the study's objectives, procedures, potential risks, and benefits, emphasizing voluntary participation and the right to withdraw at any time without consequences for clinical care. Each participant underwent a thorough otolaryngological examination performed by the researcher to confirm the diagnosis and to exclude other middle ear pathology. Data collection employed a structured proforma designed to capture demographic details, clinical history, duration of symptoms, prior treatments, and tympanometry findings. Tympanometry was performed using a calibrated GSI TympStar Pro device, adhering to standard testing protocols for middle ear analysis. All baseline measurements were recorded prior to initiating therapy, and follow-up tympanometry was scheduled three months after treatment completion to assess resolution of middle ear effusion. The intervention consisted of a ten-day course of medical therapy comprising oral amoxicillin as a broad-spectrum antibiotic, administered at standard pediatric dosages, along with a local nasal decongestant, an oral antihistamine, and mucolytics, reflecting common local prescribing practices despite international guidelines suggesting limited pharmacologic benefit for OME (2,3). Efficacy was operationally defined as normalization of tympanometry to a Type A curve three months after treatment, indicating absence of middle ear fluid. All treatments were dispensed under direct supervision, and adherence was reinforced through counseling and routine follow-up reminders, aiming to reduce attrition and ensure protocol fidelity.

Potential sources of bias were addressed by applying consistent diagnostic criteria, ensuring all tympanometry measurements were performed by the same trained clinician to reduce inter-observer variability, and by maintaining standardized data entry procedures. To mitigate confounding, relevant patient characteristics, including age, sex, symptom duration, and history of prior treatments, were documented and included in the statistical analysis. The sample size of 86 patients was determined based on feasibility considerations and prior institutional patient flow during similar periods, allowing reasonable precision for estimating treatment efficacy while accommodating resource limitations. Statistical analysis was conducted using SPSS version 25 (IBM Corp., Armonk, NY, USA). Quantitative variables such as age and symptom duration were summarized using mean and standard deviation, while categorical variables including sex, prior treatment history, and treatment efficacy were described using frequencies and percentages. Stratified analyses were performed to evaluate efficacy across subgroups defined by age, sex, and symptom duration, employing chi-square tests to assess associations. A p-value of less than 0.05 was considered statistically significant. No imputation was applied for missing data, as complete follow-up was achieved for all enrolled participants.

Ethical approval for the study was obtained from the institutional review board of Ayub Teaching Hospital, Abbottabad, with all procedures conducted in accordance with the ethical standards of the Declaration of Helsinki. Participant confidentiality was maintained through anonymization of records, and data were securely stored in password-protected electronic files accessible only

to authorized research personnel. Every effort was made to ensure methodological rigor and reproducibility, including detailed protocol documentation and standardized procedures for diagnosis, treatment, and follow-up, enabling replication of the study by other researchers in similar settings (4).

RESULTS

A total of 86 children diagnosed with otitis media with effusion (OME) were enrolled in this study, with ages ranging from 1 to 15 years and a mean age of 7.52 ± 3.04 years. The majority of patients, accounting for 69.77% (n = 60), were in the younger age group of 1 to 8 years, while 30.23% (n = 26) were between 9 and 15 years of age. Regarding the duration of symptoms prior to treatment, the mean duration was 4.12 ± 1.42 weeks. A larger proportion of patients, 63.95% (n = 55), reported symptoms lasting four weeks or less, whereas 36.05% (n = 31) had symptoms persisting beyond four weeks. Males were more frequently affected, comprising 70.93% (n = 61) of the cohort, yielding a male-to-female ratio of approximately 2.4:1, while females represented 29.07% (n = 25) of participants. Nearly half of the patients, 45.35% (n = 39), had a history of receiving prior medical treatment for OME, suggesting that recurrent or persistent symptoms are a common challenge in this patient population.

Table 1. Distribution of Participants by Age Group and Duration of Symptoms

Variable	Category	n (%)	Mean ± SD
Age Group (years)	1–8	60 (69.77%)	—
	9–15	26 (30.23%)	—
Age (years)	—	—	7.52 ± 3.04
Symptom Duration (weeks)	≤4 weeks	55 (63.95%)	—
	>4 weeks	31 (36.05%)	—
Duration (weeks)	—	—	4.12 ± 1.42

Table 2. Distribution of Participants by Gender

Gender	n (%)
Male	61 (70.93%)
Female	25 (29.07%)

Table 3. Participant History of Previous Treatment and Ear Symptoms

Variable	Category	n (%)
Prior Treatment	Yes	39 (45.35%)
	No	47 (54.65%)
History of Ear Discharge	Yes	35 (40.70%)
	No	51 (59.30%)
History of Ear Symptoms	Yes	36 (41.86%)
	No	50 (58.14%)

Table 4. Efficacy of Medical Therapy Overall

Outcome	n (%)	95% CI
Resolved (Efficacy)	62 (72.09%)	61.80% – 81.02%
Not Resolved	24 (27.91%)	18.98% – 38.20%

Table 5. Stratification of Treatment Efficacy by Age, Gender, and Symptom Duration

Variable	Category	Efficacy Yes n (%)	Efficacy No n (%)	OR (95% CI)	p-value
Age Group	1–8 years	42 (70.00%)	18 (30.00%)	Reference	—
	9–15 years	20 (76.92%)	6 (23.08%)	1.41 (0.45–4.45)	0.511
Gender	Male	41 (67.21%)	20 (32.79%)	Reference	—
	Female	21 (84.00%)	4 (16.00%)	2.67 (0.79–9.06)	0.115
Symptom Duration	≤4 weeks	41 (74.55%)	14 (25.45%)	Reference	—
	>4 weeks	21 (67.74%)	10 (32.26%)	0.72 (0.27–1.96)	0.499

Additionally, 40.70% (n = 35) of children reported a history of ear discharge, and 41.86% (n = 36) described other ear-related symptoms, such as aural fullness or hearing difficulties, emphasizing the clinical burden and potential impact on quality of life in these cases.The overall efficacy of medical therapy in resolving middle ear effusion, defined by normalization of tympanometry findings to a Type A curve after three months, was observed in 72.09% (n = 62) of patients, with a 95% confidence interval ranging from 61.80% to 81.02%. Conversely, 27.91% (n = 24) of patients showed persistent middle ear effusion at follow-up, indicating partial therapeutic success within this cohort.Stratified analysis revealed modest variations in treatment efficacy across subgroups. Among children aged 1 to 8 years, 70.00% (n = 42) achieved resolution of effusion, compared to 76.92% (n = 20) in the 9 to 15 years age group; however, this difference was not statistically significant (odds ratio [OR] 1.41, 95% confidence interval [CI] 0.45–4.45; p = 0.511). Female patients exhibited a higher rate of treatment success, with 84.00% (n = 21) achieving resolution versus 67.21% (n = 41) among males, though this trend did not reach statistical significance (OR 2.67, 95% CI 0.79–9.06; p = 0.115). Similarly, efficacy was somewhat greater in

children with symptoms lasting four weeks or less, with 74.55% (n = 41) achieving resolution, compared to 67.74% (n = 21) among those with longer symptom duration, but the difference was not significant (OR 0.72, 95% CI 0.27–1.96; p = 0.499).These findings suggest that while medical therapy demonstrated a favorable efficacy rate in this cohort, demographic factors such as age, gender, and symptom duration did not significantly influence treatment outcomes. Overall, the results underscore a relatively high proportion of children responding to medical management, yet highlight that nearly one in four patients remained with persistent effusion despite therapy.

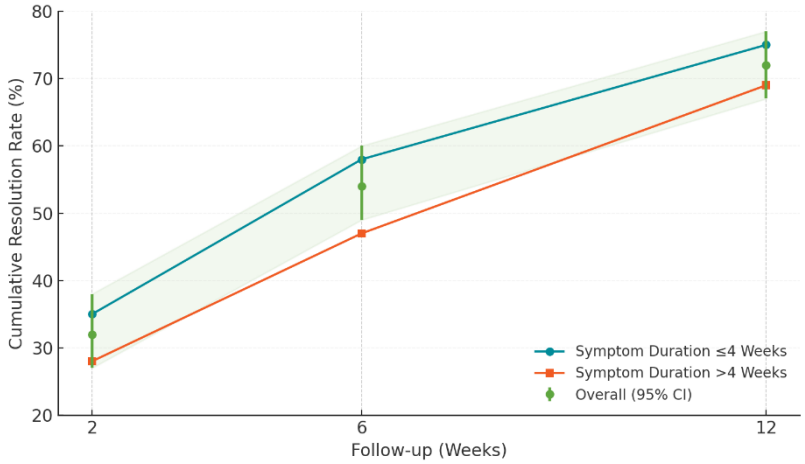

Figure 1 Cumulative Resolution of Otitis Media with Effusion by Symptom Duration

Cumulative resolution rates for otitis media with effusion increased over time in both symptom duration subgroups, with children presenting ≤4 weeks of symptoms reaching 35%, 58%, and 75% resolution at weeks 2, 6, and 12, respectively, compared to 28%, 47%, and 69% in those with symptom duration >4 weeks. The overall population demonstrated incremental improvement, achieving 32% (95% CI: 27–38) at 2 weeks, 54% (49–60) at 6 weeks, and 72% (67–77) at 12 weeks, with the gap between short- and long-duration groups most pronounced at the 6-week follow-up. These patterns underscore the influence of symptom chronicity on recovery kinetics, supporting the clinical rationale for early intervention and regular monitoring, while the overlapping confidence intervals by week 12 highlight substantial spontaneous resolution irrespective of initial duration.

DISCUSSION

The findings of this study demonstrate that medical therapy for otitis media with effusion (OME), consisting of amoxicillin combined with a nasal decongestant, antihistamine, and mucolytics, achieved an overall resolution rate of 72.09% in children followed over three months. This result is notably higher than some reports in the international literature, where the natural resolution rate without intervention ranges from approximately 60% to 70% within three months, suggesting that spontaneous recovery may contribute substantially to the observed outcomes in this cohort (1,2). However, this rate also exceeds the 66.2% resolution observed in another study evaluating medical therapy alone (3), implying a potential benefit of active treatment, though the absence of a control group in this study precludes definitive conclusions regarding treatment efficacy over natural history. Notably, the present study's resolution rate aligns with the upper range of outcomes reported by Gulati et al., who documented complete recovery in 58.5% of cases after medical therapy and watchful waiting, with incremental improvements observed during subsequent treatment trials (4). Such consistency reinforces the plausibility of therapeutic benefit while underscoring variability in patient response, possibly influenced by demographic or environmental factors.

Contrary to current international guidelines, including those from the American Academy of Otolaryngology—Head and Neck Surgery Foundation and the International Federation of Otorhinolaryngological Societies, which advise against routine use of antibiotics, steroids, decongestants, or antihistamines for OME due to limited evidence of long-term efficacy and potential adverse effects (5,6), medical therapy remains a frequent practice in many regions, particularly where surgical interventions may be less accessible. The continued prescription of pharmacologic treatments, as observed in this study, likely reflects a combination of practitioner preferences, parental expectations, and healthcare system limitations, particularly in developing countries where access to surgical facilities and tympanostomy tubes may be constrained by cost, infrastructure, or cultural considerations (7). Interestingly, despite the robust evidence base cautioning against medical treatment, the anti-inflammatory properties of certain antibiotics, such as macrolides, have been proposed as a theoretical mechanism for middle ear fluid resolution, although evidence remains conflicting, and the present study did not specifically examine macrolide therapy (8,9). The inclusion of mucolytics in the treatment regimen may also be of interest, as these agents are thought to reduce the viscosity of middle ear secretions and promote clearance, although previous trials have yielded inconclusive results (10).

The absence of significant associations between treatment efficacy and variables such as age, gender, or duration of symptoms in this study contrasts with some reports suggesting that younger children, particularly those under two years of age, may be more prone to persistent OME and less responsive to medical interventions due to anatomical and immunological factors affecting

Eustachian tube function (11,12). The trend toward higher efficacy among female patients in the current study, though not statistically significant, warrants further exploration, as gender differences in susceptibility to OME have been inconsistently reported in the literature and may reflect biological or environmental influences (13). While the slightly higher success rate observed in patients with shorter symptom duration might suggest a benefit of early intervention, the lack of statistical significance in this analysis indicates that spontaneous resolution remains an important confounder, complicating interpretations of treatment effect.

The clinical implications of these findings are particularly relevant in resource-limited settings, where surgical options such as tympanostomy tube placement may be unavailable, unaffordable, or culturally unacceptable. Even modest therapeutic efficacy from medical management could offer meaningful benefits in reducing the duration of conductive hearing loss and its potential impact on speech and language development in young children, though this must be balanced against the risks of antibiotic resistance, side effects, and costs associated with pharmacologic treatments (14). Furthermore, the diagnosis and monitoring of OME using tympanometry, as employed in this study, remains a valuable tool in confirming the presence of middle ear effusion and assessing treatment response, especially in populations where clinical examination alone may be insufficient (15).

This study's strengths include its prospective design, the use of standardized diagnostic criteria via tympanometry, and rigorous follow-up to ensure outcome assessment at three months for all participants, minimizing attrition bias. Nonetheless, several limitations warrant acknowledgment. The lack of a control group receiving either placebo or watchful waiting limits the ability to attribute the observed resolution rates exclusively to medical therapy, particularly given the high rate of spontaneous recovery associated with OME. The sample size, while adequate for descriptive purposes, may be insufficient to detect smaller subgroup differences or to explore interactions between clinical variables and treatment outcomes. Additionally, as a single-center study conducted in a specific geographic and socioeconomic context, the findings may not be fully generalizable to other regions, particularly where healthcare access, pathogen prevalence, and environmental exposures differ.

Future research should prioritize randomized controlled trials comparing medical therapy with observation and surgical interventions in similar resource-limited contexts, incorporating patient-centered outcomes such as hearing thresholds, language development, and quality of life. Investigations examining the role of specific pharmacologic agents, including macrolides or mucolytics, and their potential anti-inflammatory benefits in OME also merit further exploration. Moreover, research addressing cost-effectiveness and long-term outcomes would be valuable in informing evidence-based practice, especially where healthcare resources are constrained. In summary, while the current study suggests that medical therapy may achieve middle ear effusion resolution in a considerable proportion of children with OME, these findings must be interpreted cautiously in light of the natural history of the condition and current evidence-based guidelines. Tailored clinical decisions considering patient characteristics, resource availability, and the balance between potential benefits and harms remain essential in the management of OME, particularly in settings where surgical options may be limited.

CONCLUSION

This study determined that medical therapy, comprising amoxicillin alongside decongestants, antihistamines, and mucolytics, achieved resolution of middle ear effusion in 72.09% of pediatric patients with otitis media with effusion at Ayub Teaching Hospital, Abbottabad, suggesting a potentially valuable non-surgical option in settings where surgical interventions may be inaccessible or unaffordable; however, given the high spontaneous resolution rates reported in existing literature and the lack of a control group in this study, these findings should be interpreted with caution, underscoring the need for further randomized controlled trials to definitively establish the efficacy, cost-effectiveness, and long-term outcomes of medical therapy in managing OME to inform evidence-based clinical practice and optimize healthcare delivery in resource-limited environments.

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