ORIGINAL RESEARCH

Evaluating the effectiveness of a pharmacological intervention in reducing the incidence of otitis media in children: A community-based study

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ABSTRACT

Aim: This study aimed to evaluate the effectiveness of a pharmacological intervention in reducing the incidence of otitis media, improving hearing outcomes, and minimizing antibiotic usage in children in a community-based setting. **Material and Methods:** This prospective, community-based, interventional study included 200 children aged 6 months to 12 years from urban and semi-urban regions. Participants were selected based on recurrent otitis media history, and pharmacological intervention included prophylactic antibiotics or immunomodulators administered over six months with monthly follow-ups. Baseline assessments included medical history, ENT examinations, audiometric tests, and detailed parental education on adherence and symptom recognition. Outcomes measured included a reduction in otitis media episodes, improvements in hearing thresholds, antibiotic dependency, and adverse effects. **Results:** The intervention resulted in a significant reduction in the frequency of otitis media episodes (4.2 ± 1.5 to 1.3 ± 0.8, $p<0.001$) and improved hearing thresholds (35.5 ± 5.8 dB to 25.3 ± 4.5 dB, $p<0.001$). Antibiotic usage also decreased significantly (77.5% to 22.5%, $p<0.001$). Adverse effects were minimal, with mild gastrointestinal upset (7.5%), skin rash (4.0%), and fatigue (2.5%). Parental adherence was high, with 89% showing consistent compliance. **Conclusion:** Pharmacological intervention effectively reduced otitis media episodes, improved hearing outcomes, and decreased antibiotic dependency with minimal adverse effects. High parental adherence further contributed to successful outcomes, underscoring the intervention's effectiveness and feasibility in community-based settings.

Keywords: Otitis Media, Pharmacological Intervention, Pediatric Health, Antibiotic Dependency

INTRODUCTION

Otitis media, an inflammation or infection of the middle ear, remains one of the most common childhood diseases worldwide, contributing significantly to morbidity, healthcare costs, and antibiotic usage. It is primarily characterized by ear pain, fever, irritability, and, in severe cases, hearing loss. Otitis media is typically classified into three main types: acute otitis media (AOM), otitis media with effusion (OME), and chronic suppurative otitis media (CSOM). Among these, AOM is the most prevalent and often leads to recurrent infections if not managed effectively. The condition poses significant public health challenges, particularly in pediatric populations, where early-life infections can have long-term consequences on speech, language, and cognitive development.[1]The etiology of otitis media is multifactorial, with bacterial and viral pathogens playing central roles. Common bacterial culprits include *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Moraxella catarrhalis*. Viral infections, particularly those affecting the upper

respiratory tract, are also known to predispose children to secondary bacterial infections in the middle ear. Environmental factors, including exposure to cigarette smoke, attendance at daycare centers, and poor sanitation, further increase susceptibility. Anatomical and physiological differences in the pediatric Eustachian tube, such as its shorter and more horizontal orientation, make children particularly vulnerable to middle ear infections.[2] Despite the availability of antibiotics and improved vaccination strategies, the burden of otitis media remains substantial. Recurrent episodes are common, and frequent antibiotic use raises concerns about antibiotic resistance, adverse side effects, and disruption of normal gut microbiota. In addition, repeated infections can lead to complications such as tympanic membrane perforation, chronic hearing loss, and impaired speech and language development. These long-term consequences place a significant burden not only on affected children but also on their families and healthcare systems.[3] Pharmacological interventions have played a pivotal role in managing otitis media, primarily through the use of antibiotics, analgesics, and, in specific cases, immunomodulators. Antibiotics remain the cornerstone of treatment for bacterial otitis media, with amoxicillin being the most commonly prescribed first-line drug. However, the rise in antibiotic resistance has underscored the need for targeted and judicious antibiotic use. Prophylactic antibiotic regimens have been explored as a preventive strategy for children with recurrent otitis media, with varying degrees of success. In addition to antibiotics, analgesics such as ibuprofen and acetaminophen are widely used to alleviate pain and reduce fever, improving patient comfort and compliance.[4] Beyond antibiotics and analgesics, immunomodulatory therapies have emerged as a promising adjunct in managing recurrent otitis media. These interventions aim to enhance the child's immune response, reducing the frequency and severity of infections. Probiotics and certain vitamins, such as vitamin D, have been studied for their potential immunomodulatory effects in reducing the incidence of otitis media. Furthermore, emerging evidence suggests that addressing modifiable risk factors, such as improving hygiene, reducing environmental tobacco smoke exposure, and promoting exclusive breastfeeding, can significantly reduce the disease burden.While existing pharmacological interventions have shown promise, their effectiveness in real-world community settings remains underexplored. Most clinical trials and intervention studies are conducted in controlled healthcare environments, limiting the generalizability of findings to diverse community-based populations. A community-based approach is essential for evaluating pharmacological interventions in real-world scenarios, where factors such as healthcare access, parental adherence to treatment regimens, and socioeconomic determinants significantly influence outcomes.[5] In community settings, parental education and adherence to treatment plans play a crucial role in determining the success of pharmacological interventions. Effective communication between healthcare providers and caregivers is vital to ensure proper medication administration, timely follow-ups, and recognition of early signs of recurrence or complications. Understanding the barriers to adherence, such as forgetfulness, lack of awareness, or logistical challenges, can help design targeted interventions that address these gaps.[6] This study focuses on evaluating the effectiveness of a pharmacological intervention in reducing the incidence of otitis media in children within a community-based setting. By addressing both clinical and practical aspects of intervention delivery, the study aims to provide insights into the real-world applicability and impact of pharmacological strategies. The findings are expected to guide healthcare providers, policymakers, and public health experts in formulating evidence-based strategies for managing otitis media at the community level.

MATERIAL AND METHODS

This study was designed as a prospective, community-based, interventional study to evaluate the effectiveness of a pharmacological intervention in reducing the incidence of otitis media in children.The study included 200 children aged 6 months to 12 years who were recruited from selected community health centers and pediatric outpatient departments.The study was conducted in urban and semi-urban regions within a defined geographical area, ensuring representation from diverse socioeconomic and environmental backgrounds.

Inclusion Criteria

- Children aged 6 months to 12 years.
- Children with a history of recurrent otitis media (at least 2 episodes in the past 6 months or 3 episodes in the past year).
- Children whose parents or guardians provided written informed consent.
- Children without any ongoing acute ear infection at the time of enrollment.

Exclusion Criteria

- Children with chronic suppurative otitis media (CSOM).
- Children with congenital ear abnormalities.
- Children with immunodeficiencies or underlying chronic illnesses affecting immunity.
- Children currently on long-term antibiotic therapy for other conditions.
- Children whose parents or guardians refused consent to participate in the study.

Intervention

The pharmacological intervention included a prophylactic antibiotic regimen or an immunomodulatory agent, administered according to

standard pediatric dosing guidelines. The choice of medication was based on current clinical guidelines for otitis media prevention.

- Intervention Duration: 6 months
- Follow-up Frequency: Monthly visits for clinical assessment and compliance monitoring

Study Procedure

The study procedure began with a baseline assessment, where a detailed medical history of otitis media episodes was recorded for each participant. This included information on the frequency, duration, and severity of previous episodes. A thorough ENT examination was conducted, involving otoscopy to inspect the ear canal and eardrum, and tympanometry to assess middle ear function. Additionally, hearing function was evaluated using age-appropriate audiometric tests to establish a baseline for auditory health.

In the intervention phase, the pharmacological treatment was initiated based on standard pediatric dosing guidelines and monitored monthly. Parents and guardians received education on medication adherence, recognizing early symptoms of otitis media, and the importance of attending follow-up visits to ensure consistent monitoring and intervention compliance.

The monitoring and follow-up phase involved monthly visits over a period of six months. During each follow-up, a detailed ENT examination was repeated, and symptoms or signs of otitis media were recorded. Any new episodes of otitis media were documented meticulously. Additionally, adverse events and side effects related to the pharmacological intervention were closely monitored and addressed appropriately to ensure participant safety and treatment efficacy.

The outcome measures focused on both primary and secondary endpoints. The primary outcome was defined as a reduction in the incidence of otitis media episodes over the study duration. Secondary outcomes included improved hearing outcomes, a reduction in antibiotic usage, and a record of adverse effects associated with the intervention.

Data collection was performed systematically using structured questionnaires, clinical examination findings, and parent-reported adherence logs. The data sources included results from regular ENT assessments, participants' medical history, and caregiver-reported symptoms, ensuring a comprehensive dataset for analysis. This structured approach ensured reliable monitoring, effective intervention, and meaningful evaluation of the pharmacological treatment's impact on reducing the incidence and severity of otitis media episodes in children.

Statistical Analysis

Data were analyzed using SPSS v21.0. Descriptive statistics were used to summarize baseline characteristics. Chi-square tests and paired t-tests were employed to compare pre- and post-intervention outcomes. A p-value <0.05 was considered statistically significant.

RESULTS

Demographic Details of Study Participants (Table 1)

The study included 200 children with a mean age of 4.8 ± 2.5 years. The gender distribution was fairly balanced, with 108 males (54%) and 92 females (46%) (*p=0.421*), showing no significant gender-based differences. Regarding residence, a higher proportion of participants (114 children, 57%) came from urban areas, while 86 children (43%) were from semi-urban regions (*p=0.371*). Socioeconomic status revealed that 90 children (45%) belonged to the low socioeconomic group, 72 children (36%) to the middle group, and 38 children (19%) to the high socioeconomic group (*p=0.289*), suggesting no significant socioeconomic disparity. In terms of nutritional status, 142 children (71%) had a normal nutritional profile, while 58 children (29%) were malnourished (*p=0.315*). These findings highlight a diverse representation across gender, residence, socioeconomic status, and nutritional status, with no statistically significant differences among these demographic variables.

Baseline Characteristics Related to Otitis Media (Table 2)

The frequency of otitis media episodes in the past year showed that 85 children (42.5%) experienced 2–3 episodes, 75 children (37.5%) had 4–5 episodes, and 40 children (20%) had more than 5 episodes (*p=0.008*), indicating a significant burden of recurrent infections among the participants. In terms of previous antibiotic usage, 155 children (77.5%) had a history of antibiotic use, while 45 children (22.5%) had not used antibiotics (*p=0.014*), suggesting a high dependence on antibiotic treatments for recurrent infections. Additionally, only a small fraction of children (12 children, 6%) used hearing aids, while the vast majority (188 children, 94%) did not (*p=0.041*). These baseline findings underline a significant reliance on antibiotics and the prevalence of repeated infections among the study participants.

Effectiveness of Pharmacological Intervention on Otitis Media Episodes, Hearing Thresholds, and Antibiotic Usage (Table 3)

The intervention demonstrated a significant reduction in otitis media episodes, with the average number of episodes decreasing from 4.2 ± 1.5 pre-intervention to 1.3 ± 0.8 post-intervention (*p<0.001*). This indicates a substantial improvement in disease control. Similarly, hearing thresholds improved significantly, with pre-intervention values of 35.5 ± 5.8 dB improving to 25.3 ± 4.5 dB post-intervention (*p<0.001*), reflecting enhanced auditory health outcomes. Furthermore, the

number of children requiring antibiotic usage decreased dramatically from 155 children pre-intervention to 45 children post-intervention (*p<0.001*), signifying a significant reduction in antibiotic dependence. These findings collectively demonstrate the effectiveness of the pharmacological intervention in reducing the frequency of otitis media episodes, improving hearing function, and minimizing antibiotic reliance.

Adverse Effects of Pharmacological Intervention (Table 4)

Most children (172 children, 86%) experienced no adverse effects from the pharmacological intervention. Among those who reported side effects, 15 children (7.5%) experienced gastrointestinal upset with a mean duration of 2.5 ± 1.1 days (*p=0.032*), 8 children (4.0%) developed skin rash with a mean duration of 3.2 ± 1.3 days (*p=0.045*), and 5 children (2.5%) reported fatigue lasting approximately 1.8 ± 0.9 days (*p=0.051*). All adverse effects were classified as mild and resolved spontaneously or with minimal intervention. The overall safety profile of the pharmacological intervention was favorable, with adverse effects being minimal and transient.

Parental Adherence to Treatment Plan (Table 5)

Parental adherence to the treatment plan was high, with 178 parents (89%) demonstrating consistent compliance (*p<0.001*). A smaller proportion (17 parents, 8.5%) showed moderate adherence, with forgetfulness being the primary reason and an average of 1.1 ± 0.9 missed follow-up visits (*p=0.042*). Only 5 parents (2.5%) demonstrated low adherence, primarily due to lack of awareness and travel-related issues, with an average of 2.3 ± 1.2 missed follow-up visits (*p=0.018*). These findings suggest that the majority of parents were committed to adhering to the treatment regimen, with targeted education and communication playing a crucial role in improving compliance.

Table 1: Demographic Details of Study Participants

Variable	Number (n)	Percentage (%)	p-value
Age (Mean ± SD)	4.8 ± 2.5 years		
Gender			
Male	108	54	0.421
Female	92	46	
Residence			
Urban	114	57	0.371
Semi-Urban	86	43	
Socioeconomic Status			
Low	90	45	0.289
Middle	72	36	
High	38	19	
Nutritional Status			
Normal	142	71	0.315
Malnourished	58	29	

Table 2: Baseline Characteristics Related to Otitis Media

Variable	Number (n)	Percentage (%)	p-value
Frequency of Otitis Media Episodes (Past Year)			
2–3 Episodes	85	42.5	0.008
4–5 Episodes	75	37.5	
>5 Episodes	40	20	
Previous Antibiotic Usage			
Yes	155	77.5	0.014
No	45	22.5	
Use of Hearing Aids			
Yes	12	6	0.041
No	188	94	

Table3: Effectiveness of Pharmacological Intervention on Otitis Media Episodes, Hearing Thresholds, and Antibiotic Usage

Variable	Pre-Intervention (Mean ± SD / n)	Post-Intervention (Mean ± SD / n)	p-value	Interpretation
Number of Otitis Media Episodes	4.2 ± 1.5	1.3 ± 0.8	<0.001	Significant reduction in episode frequency
Hearing Threshold (dB)	35.5 ± 5.8	25.3 ± 4.5	<0.001	Significant improvement in hearing function

Children Requiring Antibiotics	155	45	<0.001	Significant reduction in antibiotic usage

Table 4: Adverse Effects of Pharmacological Intervention

Adverse Event	Number (n)	Percentage (%)	Severity	Duration (Days, Mean ± SD)	p-value
Gastrointestinal Upset	15	7.5	Mild	2.5 ± 1.1	0.032
Skin Rash	8	4.0	Mild	3.2 ± 1.3	0.045
Fatigue	5	2.5	Mild	1.8 ± 0.9	0.051
No Adverse Effects	172	86.0	—	—	—

Table 5: Parental Adherence to Treatment Plan

Variable	Number (n)	Percentage (%)	Reasons for Non-Adherence	Follow-Up Visits Missed (Mean ± SD)	p-value
Adherence Level					
High	178	89.0	—	0.2 ± 0.5	<0.001
Moderate	17	8.5	Forgetfulness	1.1 ± 0.9	0.042
Low	5	2.5	Lack of Awareness, Travel Issues	2.3 ± 1.2	0.018

DISCUSSION

In our study, the demographic distribution revealed a balanced gender representation, with no significant differences between males (54%) and females (46%). These findings align with a study conducted by Marchisio et al. (2010), where no significant gender differences were observed in otitis media prevalence among pediatric populations.[7] Additionally, our results showed a higher representation of urban participants (57%) compared to semi-urban areas (43%). Similar findings were reported by Teele et al. (1989), who highlighted a higher incidence of otitis media in urban areas, potentially due to increased exposure to environmental pollutants and overcrowded living conditions.[8]Socioeconomic status showed that 45% of participants belonged to the low-income group, 36% to the middle-income group, and 19% to the high-income group. These observations mirror findings from Tong et al. (1996), who identified a higher prevalence of recurrent otitis media in lower socioeconomic groups, often associated with limited access to healthcare, poor hygiene, and inadequate nutritional status.[9] Nutritional assessment revealed that 29% of participants were malnourished. This finding is consistent with Monasta et al. (2012), who reported malnutrition as a contributing factor to increased susceptibility to recurrent otitis media. Overall, the demographic data indicate a diverse participant pool and highlight the importance of socioeconomic and nutritional factors in otitis media susceptibility.[10]Our study found a high frequency of recurrent otitis media episodes, with 42.5% of participants experiencing 2–3 episodes in the past year, 37.5% experiencing 4–5 episodes, and 20% experiencing more than 5 episodes. These results are comparable to findings from Bluestone et al. (2000), who reported a similar frequency distribution of recurrent otitis media in pediatric cohorts.[11] The high reliance on antibiotics (77.5%) observed in our study aligns with results from Koivunen et al. (1999), where frequent antibiotic prescriptions were noted in children with recurrent otitis media.[12]Notably, only 6% of participants in our study used hearing aids. This is consistent with findings by Paradise et al. (1997), who reported low utilization rates of hearing aids among pediatric otitis media patients, often due to lack of awareness and stigma. These baseline characteristics underscore the chronic nature of otitis media, the dependency on antibiotic treatments, and the limited use of supportive devices like hearing aids, emphasizing the need for better management strategies.[13]The results of our study demonstrated a significant reduction in the frequency of otitis media episodes following pharmacological intervention, from an average of 4.2 ± 1.5 episodes pre-intervention to 1.3 ± 0.8 episodes post-intervention ($p<0.001$). These findings are consistent with a study by Linder et al. (2004), which showed a significant reduction in otitis media episodes with prophylactic antibiotic use.[14] Similarly, our study observed a significant improvement in hearing thresholds from 35.5 ± 5.8 dB pre-intervention to 25.3 ± 4.5 dB post-intervention ($p<0.001$). These improvements align with results from Rosenfeld et al. (1997), who reported enhanced auditory outcomes after effective management of otitis media through pharmacological treatment.[15] Furthermore, antibiotic usage reduced drastically from 77.5% pre-intervention to 22.5% post-intervention ($p<0.001$). These results are in agreement with findings by Kaleida et al. (1991), who reported decreased dependency on antibiotics following structured pharmacological interventions. Collectively, these findings demonstrate that pharmacological interventions are effective in reducing recurrent otitis media episodes, improving hearing outcomes, and minimizing antibiotic

reliance.[16]In our study, 86% of participants experienced no adverse effects from the pharmacological intervention, while mild adverse effects, including gastrointestinal upset (7.5%), skin rash (4.0%), and fatigue (2.5%), were reported. These results are consistent with findings by Venekamp et al. (2013), who reported similar mild adverse effects in children undergoing prophylactic antibiotic treatment for otitis media.[17]The mild and self-limiting nature of these adverse effects aligns with data from Leach et al. (2008), who concluded that adverse effects associated with prophylactic antibiotics are generally transient and manageable. These observations emphasize the safety and tolerability of the pharmacological intervention used in our study.[18]Parental adherence was high in our study, with 89% of parents showing consistent compliance with the intervention plan. These results are in line with findings from Rovers et al. (2006), who reported high adherence rates in structured community-based interventions for otitis media. However, moderate adherence (8.5%) and low adherence (2.5%) were observed, primarily due to forgetfulness, lack of awareness, and travel-related challenges.[19]Similar barriers to adherence were noted in a study by Morris et al. (2007), where travel-related issues and forgetfulness were identified as key factors affecting parental compliance. The low percentage of non-adherence in our study suggests that structured education and effective communication with parents played a vital role in maintaining compliance levels.[20]The observed improvements in hearing thresholds and reduced reliance on antibiotics align with global recommendations for managing recurrent otitis media in children. These findings highlight the importance of structured pharmacological interventions, effective parental education, and consistent follow-up to ensure optimal outcomes.

CONCLUSION

In conclusion, this study demonstrated that pharmacological intervention significantly reduced the incidence of otitis media episodes, improved hearing thresholds, and minimized antibiotic dependency in children. The intervention was well-tolerated, with only mild and self-limiting adverse effects reported. High parental adherence to the treatment plan played a crucial role in achieving these positive outcomes. These findings highlight the effectiveness, safety, and practicality of pharmacological interventions in managing otitis media in community-based settings, emphasizing the need for continued education and structured follow-up programs to ensure sustained benefits.

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