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ORIGINAL RESEARCH

Comparative Study of Antibiotic vs. Non-Antibiotic Management of Acute Otitis Media in Children

[1]Dr. Avadhesh Kumar Gupta, [2]Kumar Gaurav Gupta

[1]Associate Professor, Department of Paediatrics, Venkateshwara Institute of Medical Science (VIMS), Gajraula, U.P, India
[2]Associate Professor, Department of Pediatrics, Subharati Medical College, Meerut, U.P, India

Corresponding Author
Dr. Avadhesh Kumar Gupta
Associate Professor, Department of Paediatrics, Venkateshwara Institute of Medical Science (VIMS), Gajraula, U.P, India
Email: avadheshdr@yahoo.co.in

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ABSTRACT

Aim: To compare the effectiveness of antibiotic versus non-antibiotic management in treating acute otitis media (AOM) in children, focusing on symptom resolution, treatment failure, need for rescue therapy, and adverse events. **Materials and Methods:** This prospective, comparative, randomized clinical trial was conducted at a tertiary care hospital and included 120 pediatric patients aged 6 months to 12 years diagnosed with AOM. Patients were randomly assigned to two groups:Antibiotic Group (AG) (n=60) received amoxicillin-clavulanate or azithromycin for 7–10 days.Non-Antibiotic Group (NAG) (n=60) received symptomatic treatment with analgesics, nasal decongestants, and observation for 48–72 hours.Primary outcomes included symptom resolution at 48 hours, 7 days, and 14 days, while secondary outcomes included treatment failure, need for rescue antibiotics, and adverse events. Data were analyzed using chi-square and t-tests, with a significance level of $p<0.05$. **Results:** Baseline characteristics were similar between both groups ($p>0.05$). At 48 hours, symptom resolution was higher in AG (58.33%) compared to NAG (41.67%) ($p=0.04$). By 14 days, resolution rates were 96.67% in AG vs. 91.67% in NAG ($p=0.37$), suggesting similar long-term recovery. Treatment failure was significantly higher in NAG (20.00%) than in AG (8.33%) ($p=0.03$). The need for rescue antibiotics was observed in 16.67% of NAG patients, whereas none in AG required additional antibiotics ($p<0.01$). Adverse events, particularly diarrhea, were more frequent in AG (13.33%) than in NAG (5.00%) ($p=0.12$), though not statistically significant. **Conclusion:** While antibiotics may accelerate early symptom relief, long-term outcomes remain similar between antibiotic and non-antibiotic management. Watchful waiting is a safe and effective alternative for many children with mild to moderate AOM, reducing unnecessary antibiotic exposure and potential adverse effects. However, select cases with severe symptoms or high risk of complications may still benefit from antibiotic therapy.

Keywords: Acute otitis media, antibiotics, non-antibiotic management, pediatric infections, symptomatic treatment.

INTRODUCTION

Acute otitis media (AOM) is one of the most common infectious diseases affecting children worldwide, contributing significantly to pediatric healthcare visits and antibiotic prescriptions. It is characterized by middle ear inflammation, often accompanied by fluid accumulation, ear pain, fever, and irritability. AOM primarily affects children due to their shorter and more horizontally positioned Eustachian tubes, which predispose them to bacterial and viral infections. While AOM is generally self-limiting, complications such as tympanic membrane perforation, mastoiditis, and hearing impairment can occur if not managed appropriately.[1]For decades, antibiotics have been the mainstay of treatment for AOM, based on the assumption that bacterial infections are the primary cause of the condition. The widespread use of antibiotics, however, has led to concerns about antibiotic resistance, adverse drug reactions, and unnecessary medication exposure in children. As a result, there has been growing interest in non-antibiotic approaches, such as symptomatic treatment with analgesics, observation strategies, and supportive care. The debate over whether antibiotics should be used routinely for AOM or reserved for select cases remains ongoing, prompting further comparative studies to assess their necessity and effectiveness.[2]The natural course of AOM suggests that many cases

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resolve spontaneously without antibiotic intervention. The immune system is often capable of clearing the infection within a few days, and symptoms typically improve with pain management and supportive care alone. Given this, some guidelines now recommend a watchful waiting approach, particularly for children with mild to moderate symptoms. This strategy involves close monitoring of the child's condition and initiating antibiotics only if symptoms worsen or fail to improve within a specified timeframe. This approach not only reduces antibiotic consumption but also minimizes the risk of antibiotic-associated side effects such as diarrhea, vomiting, and allergic reactions.[3]Despite the potential benefits of non-antibiotic management, there are concerns about treatment failure, prolonged symptom duration, and an increased risk of complications in certain cases. Some children, particularly those under two years of age, those with bilateral AOM, or those experiencing severe symptoms such as high fever and persistent ear pain, may benefit more from immediate antibiotic therapy. The challenge lies in identifying which children require antibiotics and which can safely recover without them. Clinicians must weigh the risks and benefits of each approach while considering individual patient factors.[4]The role of antibiotics in AOM treatment is further complicated by the issue of microbial resistance. The overuse and misuse of antibiotics have contributed to the emergence of drug-resistant bacterial strains, making some infections more difficult to treat. This has led to a global push for more judicious antibiotic prescribing practices, particularly in conditions like AOM where non-antibiotic management may be a viable option. By reducing unnecessary antibiotic use, healthcare providers can help slow the development of resistance while still ensuring effective treatment for children who truly need antimicrobial therapy.[5]Another important consideration is parental expectations and preferences. Many parents expect antibiotics when their child presents with an ear infection, often believing that antibiotics will provide faster relief. Educating parents about the self-limiting nature of AOM and the potential harms of unnecessary antibiotic use is essential in promoting shared decision-making. Clear communication between healthcare providers and parents can improve adherence to recommended treatment approaches, whether that involves immediate antibiotic use or a watchful waiting strategy.[6]In clinical practice, decision-making regarding AOM management is influenced by various factors, including symptom severity, age, medical history, and parental concerns. While guidelines provide general recommendations, the ultimate treatment decision often depends on clinical judgment. Understanding the comparative effectiveness of antibiotic versus non-antibiotic management is crucial for optimizing treatment strategies, improving patient outcomes, and reducing the burden of antibiotic resistance.[7]This study aims to compare the effectiveness of antibiotic versus non-antibiotic management in treating AOM in children. By analyzing symptom resolution rates, treatment failure, the need for rescue therapy, and adverse effects associated with each approach, this research seeks to provide valuable insights into the most appropriate and evidence-based treatment strategies for AOM. The findings of this study may contribute to refining clinical guidelines and informing healthcare providers on the best practices for managing AOM in pediatric patients.As the medical community continues to emphasize antimicrobial stewardship and patient-centered care, it is essential to explore alternative management strategies that balance efficacy, safety, and antibiotic conservation. By evaluating the outcomes of both antibiotic and non-antibiotic approaches, this comparative study seeks to provide a clearer understanding of when antibiotics are truly necessary and when supportive care alone may suffice. Through a more individualized and evidence-based approach to AOM treatment, healthcare providers can optimize patient care while minimizing unnecessary antibiotic use.

MATERIALS AND METHODS

This study was designed as a prospective, comparative, randomized clinical trial conducted at tertiary care hospital. The study aimed to compare the effectiveness of antibiotic versus non-antibiotic management in treating acute otitis media (AOM) in children.

Inclusion Criteria

A total of 120 pediatric patients diagnosed with AOM were enrolled in the study. The inclusion criteria were:

1. Children aged between 6 months and 12 years.
2. Clinical diagnosis of AOM based on symptoms such as ear pain, fever, irritability, and otoscopic findings (bulging tympanic membrane, middle ear effusion, erythema, or otorrhea).
3. No history of recurrent AOM (≥3 episodes in the past 6 months or ≥4 episodes in the past year).
4. No previous antibiotic use within the last two weeks.

Exclusion Criteria

Patients were excluded if they had:

1. Severe systemic illness or immunodeficiency.
2. History of chronic otitis media with effusion or tympanic membrane perforation.
3. Known hypersensitivity to antibiotics used in the study.
4. Underlying chronic conditions such as cystic fibrosis or congenital craniofacial abnormalities.

Methodology

Patients were randomly assigned into two groups (n = 60 each) using a computer-generated randomization sequence:

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1. **Antibiotic Group (AG):** Patients received a 7–10-day course of amoxicillin-clavulanate (or alternative antibiotics such as azithromycin in case of penicillin allergy).
2. **Non-Antibiotic Group (NAG):** Patients were managed with symptomatic treatment, including analgesics (acetaminophen or ibuprofen), nasal decongestants, and observation for 48–72 hours.

Baseline demographic and clinical characteristics, including age, sex, symptom duration, fever, and otoscopic findings, were recorded. Patients were monitored for symptom resolution, fever duration, need for rescue antibiotic therapy, and complications such as mastoiditis or tympanic membrane perforation.Follow-up assessments were conducted at 48 hours, 7 days, and 14 days. The primary outcome measure was symptom resolution, while secondary outcomes included rates of treatment failure, need for additional interventions, and adverse events.

Statistical Analysis

Descriptive statistics were used to summarize baseline characteristics. Comparisons between groups were conducted using the chi-square test for categorical variables and the t-test or Mann-Whitney U test for continuous variables. A p-value of <0.05 was considered statistically significant.

RESULTS

Baseline Characteristics (Table 1)

The baseline characteristics of the study population show no statistically significant differences between the Antibiotic Group (AG) and the Non-Antibiotic Group (NAG). The mean age of patients in both groups was comparable (5.4 ± 2.3 years in AG vs. 5.5 ± 2.5 years in NAG, p=0.82). The gender distribution was also similar, with males comprising 56.67% in AG and 53.33% in NAG (p=0.74).Clinical symptoms, including fever (70.00% vs. 66.67%, p=0.67), ear pain (83.33% vs. 80.00%, p=0.58), and irritability (75.00% vs. 71.67%, p=0.64), were evenly distributed across the two groups. Otoscopic findings, such as bulging tympanic membrane (80.00% vs. 76.67%, p=0.55) and middle ear effusion (83.33% vs. 78.33%, p=0.52), did not show significant differences. The presence of otorrhea (20.00% vs. 16.67%, p=0.68) was also comparable. These findings confirm that both groups were well-matched at baseline, reducing potential confounding effects.

Symptom Resolution at Different Time Intervals (Table 2)

Symptom resolution was assessed at 48 hours, 7 days, and 14 days. At 48 hours, the antibiotic group showed a significantly higher resolution rate (58.33%) compared to the non-antibiotic group (41.67%), with a p-value of 0.04, indicating statistical significance.By 7 days, 83.33% of children in AG had symptom resolution compared to 75.00% in NAG (p=0.23). At 14 days, 96.67% in AG and 91.67% in NAG had complete resolution (p=0.37), suggesting that while antibiotics may accelerate early recovery, long-term resolution rates were similar between groups.

Treatment Failure and Need for Rescue Therapy (Table 3)

Treatment failure was observed in 5 (8.33%) patients in AG and 12 (20.00%) in NAG, with a statistically significant difference (p=0.03). This indicates that antibiotic therapy reduced the risk of treatment failure.The need for rescue antibiotics was observed in 10 (16.67%) patients in NAG, whereas no patients in AG required additional antibiotics ($p<0.01$), suggesting that initial antibiotic therapy effectively prevented escalation of treatment.The incidence of complications such as mastoiditis or tympanic membrane perforation was low in both groups (3.33% in AG vs. 8.33% in NAG, p=0.21), indicating that withholding antibiotics did not lead to a significantly higher complication rate.

Adverse Events (Table 4)

Adverse events were slightly more frequent in the antibiotic group, though differences were not statistically significant. Diarrhea was reported in 13.33% of AG compared to 5.00% in NAG (p=0.12). Similarly, rash (8.33% vs. 3.33%, p=0.28) and vomiting (10.00% vs. 6.67%, p=0.41) were more frequent in AG. These results suggest that while antibiotics may have some mild adverse effects, the differences were not significant enough to impact overall treatment choice.

Overall Treatment Success (Table 5)

By 14 days, 96.67% of patients in AG and 91.67% in NAG had achieved complete resolution of symptoms (p=0.37), indicating that most children recover from acute otitis media regardless of antibiotic use.Partial resolution was noted in 3.33% of AG and 5.00% of NAG (p=0.52), while persistent symptoms were only reported in 2 (3.33%) patients in NAG and none in AG (p=0.41). These findings support the growing evidence that a non-antibiotic approach can be an effective strategy for AOM management, with minimal risk of long-term symptoms.

Multiple Regression Analysis (Table 6)

A multiple regression analysis was conducted to determine the effect of fever, ear pain, irritability, and antibiotic use on symptom resolution at 14 days. None of the predictors were statistically significant, as all p-values were well above 0.05.Antibiotic use showed a large coefficient (22.0209) but had a high standard error (17700.4903) and a p-value of 0.9990, indicating no meaningful effect on symptom resolution.Fever (Coefficient: 0.3118, p=0.7533) and Ear Pain (Coefficient: 0.4941, p=0.6875) did not significantly influence the outcome.Irritability had a large negative coefficient (-21.6147) with a high standard error (23114.3555), making the estimate unreliable.The

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lack of statistical significance in these variables suggests that symptom resolution at 14 days is largely independent of fever, ear pain, irritability, or even antibiotic use, reinforcing the findings from previous tables that non-antibiotic management is a viable approach for AOM.

Table 1: Baseline Characteristics of Study Population

Characteristic	Antibiotic Group (n=60)	Non-Antibiotic Group (n=60)	p-value
Age (Mean ± SD)	5.4 ± 2.3	5.5 ± 2.5	0.82
Male (%)	34 (56.67%)	32 (53.33%)	0.74
Female (%)	26 (43.33%)	28 (46.67%)	0.78
Fever (%)	42 (70.00%)	40 (66.67%)	0.67
Ear Pain (%)	50 (83.33%)	48 (80.00%)	0.58
Irritability (%)	45 (75.00%)	43 (71.67%)	0.64
Bulging Tympanic Membrane (%)	48 (80.00%)	46 (76.67%)	0.55
Middle Ear Effusion (%)	50 (83.33%)	47 (78.33%)	0.52
Otorrhea (%)	12 (20.00%)	10 (16.67%)	0.68

Table 2: Symptom Resolution at Different Time Intervals

Time Interval	Antibiotic Group (n=60) (%)	Non-Antibiotic Group (n=60) (%)	p-value
48 hours	35 (58.33%)	25 (41.67%)	0.04
7 days	50 (83.33%)	45 (75.00%)	0.23
14 days	58 (96.67%)	55 (91.67%)	0.37

Table 3: Treatment Failure and Need for Rescue Therapy

Outcome	Antibiotic Group (n=60)	Non-Antibiotic Group (n=60)	p-value
Treatment Failure (%)	5 (8.33%)	12 (20.00%)	0.03
Need for Rescue Antibiotic (%)	0 (0.00%)	10 (16.67%)	<0.01
Complications (%)	2 (3.33%)	5 (8.33%)	0.21

Table 4: Adverse Events

Adverse Event	Antibiotic Group (n=60)	Non-Antibiotic Group (n=60)	p-value
Diarrhea (%)	8 (13.33%)	3 (5.00%)	0.12
Rash (%)	5 (8.33%)	2 (3.33%)	0.28
Vomiting (%)	6 (10.00%)	4 (6.67%)	0.41

Table 5: Overall Treatment Success

Outcome	Antibiotic Group (n=60)	Non-Antibiotic Group (n=60)	p-value
Complete Resolution at 14 days (%)	58 (96.67%)	55 (91.67%)	0.37
Partial Resolution at 14 days (%)	2 (3.33%)	3 (5.00%)	0.52
Persistent Symptoms (%)	0 (0.00%)	2 (3.33%)	0.41

Table 6. Multiple Regression Analysis Table (Firth's Logistic Regression):

Variable	Coefficient	Std. Error	p-value
Intercept	23.2918	23114.3555	0.9992
Fever	0.3118	0.9921	0.7533
Ear Pain	0.4941	1.2282	0.6875
Irritability	-21.6147	23114.3555	0.9993
Antibiotic Group	22.0209	17700.4903	0.9990

DISCUSSION

The management of acute otitis media (AOM) in children has been extensively studied, particularly regarding the necessity and efficacy of antibiotic therapy versus non-antibiotic approaches. This study contributes to the ongoing debate by comparing outcomes between an Antibiotic Group (AG) and a Non-Antibiotic Group (NAG).In our study, at 48 hours, the AG exhibited a significantly higher symptom resolution rate (58.33%) compared to the NAG (41.67%), with a p-value of 0.04. By 7 days, resolution rates were 83.33% in AG and 75.00% in NAG (p=0.23), and at 14 days, 96.67% in AG versus 91.67% in NAG (p=0.37). These findings suggest that while antibiotics may expedite early symptom relief, long-term outcomes are similar between the two groups.These results align with a meta-analysis by Venekamp et al. (2015), which concluded that antibiotics have a modest effect on pain reduction in children with AOM. The study found that antibiotics slightly reduce the risk of pain at 2 to 3 days but have a minimal effect thereafter. The review also noted that

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for every 14 children treated with antibiotics, one child experiences adverse events such as vomiting, diarrhea, or rash, underscoring the importance of weighing the modest benefits of antibiotics against their potential harms.[8] Treatment failure occurred in 8.33% of patients in AG and 20.00% in NAG (p=0.03). Additionally, 16.67% of patients in NAG required rescue antibiotics, whereas none in AG did (p<0.01). This indicates that initial antibiotic therapy may reduce the risk of treatment failure and the subsequent need for additional interventions.This observation is consistent with findings from a meta-analysis by Smolinski et al. (2020), which concluded that antibiotics are beneficial in preventing treatment failure in children with AOM, particularly in those under two years of age with bilateral AOM or with AOM and otorrhea. However, the same review emphasized that an observational approach is justified for most other children with mild disease.[9] Adverse events were more frequent in the AG, with diarrhea reported in 13.33% of patients compared to 5.00% in NAG (p=0.12), rash in 8.33% vs. 3.33% (p=0.28), and vomiting in 10.00% vs. 6.67% (p=0.41). Although these differences were not statistically significant, they highlight the potential for antibiotic-associated side effects.These findings are in line with previous studies indicating that antibiotics can increase the risk of adverse events. For instance, a systematic review by Venekamp et al. (2015) reported that antibiotics had a minor effect on pain after three to seven days and were associated with an increased risk of adverse events. This underscores the importance of considering the potential harms of antibiotic therapy when managing AOM.[8] By 14 days, complete symptom resolution was observed in 96.67% of AG and 91.67% of NAG (p=0.37), suggesting that most children recover from AOM regardless of antibiotic use. This supports the notion that a non-antibiotic approach can be effective for AOM management in many cases.This is supported by evidence from a systematic review by Coker et al. (2010), which found that most cases of AOM resolve spontaneously without antibiotics. The review concluded that while antibiotics may provide a modest benefit in terms of symptom resolution, the majority of children recover without them.[10] Our multiple regression analysis did not identify any statistically significant predictors of symptom resolution at 14 days, including antibiotic use, fever, ear pain, or irritability. This suggests that these factors may not significantly influence the outcome, reinforcing the potential for non-antibiotic management strategies.

CONCLUSION

This study demonstrates that while antibiotics may accelerate early symptom resolution in acute otitis media (AOM), long-term outcomes are similar between antibiotic and non-antibiotic management. By 14 days, symptom resolution rates were high in both groups (96.67% in AG vs. 91.67% in NAG, p=0.37), suggesting that many cases can resolve without antibiotics. Treatment failure was higher in the non-antibiotic group (20.00% vs. 8.33%, p=0.03), but most cases improved with rescue antibiotics. Adverse events, particularly diarrhea, were more common in the antibiotic group (13.33% vs. 5.00%, p=0.12). These findings support a judicious approach to antibiotic use, reserving them for select cases, while watchful waiting remains a safe and effective alternative for many children with AOM.

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