

LOW-DOSE VS STANDARD-DOSE AMOXICILLIN FOR UNCOMPLICATED PEDIATRIC COMMUNITY-ACQUIRED PNEUMONIA: A PRAGMATIC TRIAL

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ABSTRACT

Background: Community-acquired pneumonia (CAP) remains one of the leading causes of illness among children globally, despite advances in vaccination and antimicrobial therapy. Amoxicillin continues to be the first-line treatment for uncomplicated pediatric CAP; however, the optimal dosing strategy remains uncertain. High-dose regimens are traditionally used to overcome potential pneumococcal resistance, yet lower doses may be equally effective while reducing adverse effects, cost, and antimicrobial pressure. **Aim:** This study aimed to compare the clinical effectiveness and safety of low-dose versus standard-dose oral amoxicillin in the management of uncomplicated pediatric community-acquired pneumonia treated at a tertiary care hospital. **Materials and Methods:** A prospective, randomized, open-label, pragmatic clinical trial was conducted in a tertiary care teaching hospital. A total of 104 children aged 2 months to 12 years, clinically diagnosed with uncomplicated CAP based on WHO criteria, were enrolled and randomized into two groups (n=52 each). Group A received low-dose amoxicillin (30 mg/kg/day), while Group B received standard-dose amoxicillin (90 mg/kg/day), both administered orally in two divided doses. Clinical evaluation was performed at baseline, Day 3, and Day 7, including assessment of symptoms, vital signs, and adverse events. Laboratory parameters such as C-reactive protein (CRP) and chest radiographs were obtained as indicated. Statistical analysis was performed using SPSS version 26.0, with $p < 0.05$ considered significant. **Result:** The overall clinical cure rate was 94.23% in the low-dose group and 96.15% in the standard-dose group ($p=0.65$). Mean duration for fever resolution was 2.43 ± 0.94 days in the low-dose group versus 2.24 ± 0.86 days in the standard-dose group ($p=0.28$). Cough resolved within 4.37 ± 1.21 and 4.16 ± 1.09 days, respectively ($p=0.41$). CRP reduction and radiological improvement were similar in both groups ($p>0.05$). Adverse events were mild, occurring in 15.38% of children in each group, with no significant difference ($p=1.00$). **Conclusion:** Low-dose amoxicillin was found to be equally effective and well-tolerated as standard-dose therapy for uncomplicated pediatric CAP. These findings support the use of lower amoxicillin doses as a safe, cost-effective, and stewardship-aligned alternative in appropriate clinical settings.

INTRODUCTION

Community-acquired pneumonia (CAP) remains one of the most important infectious causes of childhood morbidity worldwide despite substantial declines in mortality over the past two decades. Global burden analyses continue to place lower respiratory infections among the leading causes of death and disability in children, particularly in low- and middle-income countries where healthcare access, vaccination coverage, and malnutrition interact to amplify risk.^[1] Even in high-income settings with

robust immunization programs, CAP drives significant healthcare utilization, including emergency visits and hospitalizations, underscoring that improvements in prevention have not eliminated the clinical and stewardship challenges of treatment selection, dose, and duration.^[2] The etiologic landscape of pediatric CAP has shifted in the post-pneumococcal conjugate vaccine (PCV) era. Large prospective studies demonstrate that while *Streptococcus pneumoniae* remains clinically relevant, viral pathogens account for a substantial share of cases and mixed infections are common, complicating empiric antimicrobial decisions.^[2]

Against this backdrop, amoxicillin continues to be recommended as first-line therapy for uncomplicated CAP because of its excellent oral bioavailability, safety profile, narrow spectrum against typical bacterial etiologies, and favorable cost—properties that are particularly valuable in pragmatic, ambulatory care models designed to reduce unnecessary hospitalizations and preserve access.^[3,4] Yet the optimal dose of amoxicillin for children with uncomplicated CAP remains debated. Historically, higher daily doses (often 80–90 mg/kg/day) were adopted in regions concerned about pneumococcal non-susceptibility, with the goal of achieving drug exposures that reliably exceed pathogen minimum inhibitory concentrations (MICs). This strategy is grounded in β -lactam pharmacodynamics: for time-dependent agents like amoxicillin, the fraction of the dosing interval during which free drug concentrations remain above the MIC ($fT > MIC$) best predicts bacterial kill and clinical response, with target exposures typically around 40–50% of the interval for penicillins.^[5] However, if circulating pneumococcal MICs are low because of vaccine effects, local resistance ecology, or case mix lower daily doses may still satisfy pharmacodynamic targets while reducing gastrointestinal adverse effects, selection pressure, and cost. Evidence supporting dose-sparing and site-of-care-sparing approaches has accumulated in related pediatric pneumonia contexts. The landmark multicenter equivalence (APPIS) trial demonstrated that oral amoxicillin is as effective as parenteral penicillin for WHO-defined severe pneumonia in children aged 3–59 months, with similar failure rates at 48 hours and comparable recovery by days 5 and 14.^[4] Building on that principle, subsequent randomized work in South Asia showed that carefully selected children with severe pneumonia could be managed safely at home with high-dose oral amoxicillin, reducing the need for inpatient care without compromising outcomes.^[4] Although these studies focused on severity categories and site of care rather than dose comparisons within uncomplicated disease, they reinforce a broader paradigm: when clinical criteria are stringent and follow-up is reliable, streamlined regimens can deliver outcomes comparable to traditional hospital-centric strategies. At the same time, stewardship considerations argue for right-sizing both dose and duration. From a microbiologic perspective, higher doses may accelerate clearance but also increase the risk of antibiotic-associated diarrhea and other adverse events, potentially eroding adherence in real-world settings. Importantly, ecological and carriage studies suggest that dosing and duration influence selection for resistant pneumococci in the nasopharynx—a key reservoir for transmission. Early randomized data indicated that short-course, high-dose amoxicillin could reduce post-treatment carriage of resistant *S. pneumoniae* compared with longer, lower-dose regimens, highlighting that exposure patterns not just total milligrams shape resistance dynamics.^[6] In communities with lower

pneumococcal MICs, however, a lower total daily dose administered over guideline-concordant durations may achieve clinical cure while minimizing unnecessary exposure and collateral effects. Guideline bodies increasingly emphasize tailoring ambulatory CAP management to disease severity, host factors, and local resistance, while encouraging oral therapy wherever feasible. The UK National Institute for Health and Care Excellence (NICE) antimicrobial prescribing guideline for community-acquired pneumonia, which covers children as well as adults, recommends amoxicillin as a first-choice oral agent in non-severe illness and explicitly frames dose and course length within antimicrobial stewardship principles, urging clinicians to use the lowest effective dose for the shortest effective duration consistent with clinical response.^[7] Such guidance aligns with pragmatic trial designs that focus on outcomes meaningful to patients and systems—time to recovery, need for retreatment or escalation, adverse events, and healthcare utilization—rather than solely microbiologic endpoints.

MATERIALS AND METHODS

This was a prospective, randomized, open-label, pragmatic clinical trial conducted at a tertiary care teaching hospital. The study was designed to compare the clinical effectiveness and safety of low-dose versus standard-dose oral amoxicillin in pediatric patients diagnosed with uncomplicated community-acquired pneumonia (CAP). All procedures were performed in accordance with institutional ethical standards and the Declaration of Helsinki. Ethical approval was obtained from the institutional ethics committee prior to initiation of the study. Informed written consent was obtained from the parents or legal guardians of all participating children before enrolment. A total of 104 pediatric patients were enrolled in the study. Children aged between two months and twelve years who presented to the pediatric outpatient department or emergency unit with a clinical diagnosis of uncomplicated community-acquired pneumonia were included. The diagnosis of CAP was made according to the World Health Organization (WHO) criteria, which included the presence of fever, cough, tachypnea, and clinical signs of lower respiratory tract involvement such as crepitations or decreased breath sounds on auscultation. Children who met these diagnostic criteria and were clinically stable were considered eligible for inclusion. Children with severe pneumonia or complications such as empyema or pleural effusion were excluded. Additional exclusion criteria included prior antibiotic use within the preceding forty-eight hours, known hypersensitivity or allergy to penicillin or β -lactam antibiotics, and the presence of significant comorbid conditions such as congenital heart disease,

immunodeficiency disorders, or chronic pulmonary diseases.

Methodology: Eligible participants were randomly assigned into two equal groups, with fifty-two children in each arm, using a computer-generated simple randomization sequence to ensure unbiased allocation. Group A, designated as the low-dose group, received oral amoxicillin at a dosage of 30 mg/kg/day divided into two equal doses. Group B, designated as the standard-dose group, received oral amoxicillin at a dosage of 90 mg/kg/day divided into two equal doses. The duration of therapy was determined according to standard national pediatric pneumonia management guidelines.

Parental counseling was provided at the time of enrolment to ensure proper adherence to the medication regimen, and compliance was reinforced through daily follow-up communication either in person or by telephone. No placebo control group was included in the design, in keeping with the pragmatic nature of the trial, which aimed to simulate real-world clinical practice rather than a tightly controlled experimental environment.

All enrolled patients were clinically evaluated at baseline and subsequently during follow-up visits on the third and seventh days after initiation of therapy. During each visit, a thorough clinical assessment was conducted, including measurement of vital signs such as temperature, respiratory rate, heart rate, and oxygen saturation. Respiratory parameters were closely observed, including the presence of chest indrawing, wheeze, crepitations, and signs of respiratory distress. A detailed systemic examination was also carried out to assess the child's general condition, feeding ability, and level of alertness.

Treatment success was defined as complete resolution of clinical signs and symptoms without the need for additional or alternative antibiotic therapy. Conversely, treatment failure was defined as the persistence or worsening of symptoms, the appearance of new complications, or the requirement for escalation of antibiotic therapy. All adverse events such as rash, vomiting, or diarrhea were recorded and evaluated for their possible relationship to the study drug.

Baseline investigations were conducted for all participants and included a complete blood count and measurement of C-reactive protein (CRP) levels to assess the inflammatory response. Chest radiography was performed at baseline to confirm the diagnosis of pneumonia and to exclude cases with severe or complicated disease. Follow-up radiographs were obtained in patients who exhibited incomplete clinical recovery or worsening symptoms during the follow-up period. All laboratory and imaging investigations were performed at the hospital's central diagnostic laboratory using standardized equipment and procedures to ensure accuracy and reproducibility of results.

The primary outcome of the study was the clinical cure rate assessed on the seventh day following initiation of antibiotic therapy. Clinical cure was

defined as the complete resolution of symptoms and physical signs of pneumonia without the need for further antibiotics. Secondary outcomes included the duration of fever and cough resolution, rate of treatment failure or relapse within seven days post-treatment, incidence of adverse drug reactions, and comparison of hospitalization rates between the two groups. These parameters were selected to provide a comprehensive assessment of both the efficacy and safety of the two dosing regimens.

Statistical Analysis

All data were collected prospectively using predesigned case record forms and subsequently entered into a secured digital database for analysis. Data processing and statistical analysis were performed using the Statistical Package for the Social Sciences (SPSS) software, version 26.0 (IBM Corp., Armonk, NY, USA). Baseline demographic and clinical characteristics were summarized using descriptive statistics, with continuous variables expressed as mean \pm standard deviation (SD) and categorical variables expressed as frequencies and percentages. Comparisons between the two study groups were made using the Chi-square test or Fisher's exact test for categorical variables and the Student's t-test or Mann-Whitney U test for continuous variables, depending on data distribution. Statistical significance was determined at a p-value less than 0.05. The results of these analyses were used to assess whether low-dose amoxicillin was non-inferior to standard-dose amoxicillin in the treatment of uncomplicated pediatric community-acquired pneumonia.

RESULTS

Table 1. Baseline Demographic and Clinical Characteristics of Study Participants

Table 1 presents the baseline demographic and clinical characteristics of the children enrolled in the study. The mean age of children in the low-dose group was 5.48 ± 2.36 years, while that in the standard-dose group was 5.62 ± 2.29 years, indicating that both groups were similar in age distribution ($p = 0.78$). The proportion of male participants was also comparable between the groups, with 53.85% males in the low-dose group and 57.69% in the standard-dose group ($p = 0.69$). The mean body weight was 17.86 ± 3.42 kg in the low-dose group and 18.22 ± 3.18 kg in the standard-dose group, showing no statistically significant difference ($p = 0.54$). Similarly, clinical baseline parameters such as respiratory rate and body temperature were nearly identical between both treatment arms. The mean respiratory rate was 38.47 ± 5.26 breaths/min in the low-dose group and 39.12 ± 4.91 breaths/min in the standard-dose group ($p = 0.46$). The average temperature at presentation was $38.12 \pm 0.64^\circ\text{C}$ in the low-dose group compared to $38.24 \pm 0.69^\circ\text{C}$ in the standard-dose group ($p = 0.38$). The mean baseline C-reactive protein (CRP) levels were 12.84 ± 4.23

mg/L in the low-dose group and 13.26 ± 4.11 mg/L in the standard-dose group, which was not significantly different ($p = 0.57$).

Table 2. Comparison of Clinical Outcomes Between Study Groups

Table 2 illustrates the primary and secondary clinical outcomes observed in both groups. The clinical cure rate was high and comparable between the groups—94.23% in the low-dose group and 96.15% in the standard-dose group ($p = 0.65$). The treatment failure rate was slightly higher in the low-dose group (5.77%) compared to the standard-dose group (3.85%), but the difference was not statistically significant ($p = 0.65$). This indicates that low-dose amoxicillin was equally effective in achieving clinical recovery in children with uncomplicated CAP. The mean duration of fever resolution was 2.43 ± 0.94 days in the low-dose group and 2.24 ± 0.86 days in the standard-dose group, showing a slightly faster improvement in the standard-dose arm; however, this difference was not statistically significant ($p = 0.28$). Similarly, the mean duration of cough resolution was 4.37 ± 1.21 days in the low-dose group and 4.16 ± 1.09 days in the standard-dose group ($p = 0.41$).

Table 3. Adverse Events Observed During the Study

Table 3 details the adverse events recorded during the study period. The overall incidence of adverse effects was identical in both groups, with 8 (15.38%) children in each group reporting at least one mild adverse event ($p = 1.00$). The most commonly reported side effect was diarrhea, seen in 7.69% of the low-dose group and 9.62% of the standard-dose group ($p = 0.72$). Vomiting occurred in 5.77% of the low-dose group and 3.85% of the standard-dose group ($p = 0.65$), while rash was reported in only 1.92% of patients in each group ($p = 1.00$). All

adverse effects were mild and self-limiting, requiring only symptomatic management without discontinuation of therapy. Importantly, there were no severe allergic reactions, anaphylaxis, or hospitalizations due to adverse events.

Table 4. Comparison of Laboratory and Radiological Response

Table 4 compares the laboratory and radiological outcomes between the two groups. The mean baseline CRP levels were similar at 12.84 ± 4.23 mg/L in the low-dose group and 13.26 ± 4.11 mg/L in the standard-dose group ($p = 0.57$). By Day 7, CRP levels had decreased significantly within both groups, indicating effective resolution of inflammation. The mean CRP at Day 7 was 5.16 ± 2.07 mg/L in the low-dose group and 4.92 ± 2.14 mg/L in the standard-dose group ($p = 0.49$). The mean percentage reduction in CRP was 59.82% for the low-dose group and 62.91% for the standard-dose group, again showing no significant difference ($p = 0.33$). Radiological improvement, assessed through chest X-ray findings, was noted in 47 (90.38%) children in the low-dose group and 48 (92.31%) in the standard-dose group ($p = 0.71$).

Table 5. Hospitalization and Follow-up Outcomes

Table 5 summarizes hospitalization and follow-up outcomes. Only 2 (3.85%) children in the low-dose group and 1 (1.92%) in the standard-dose group required hospital admission due to persistent symptoms or poor oral intake, with no statistically significant difference ($p = 0.56$). Relapse within seven days of treatment completion was rare, occurring in 1 (1.92%) child in the low-dose group and none in the standard-dose group ($p = 0.31$). The overall treatment success rate remained high and nearly identical across both groups 94.23% for the low-dose group and 96.15% for the standard-dose group ($p = 0.65$).

Table 1: Baseline Demographic and Clinical Characteristics of Study Participants

Parameter	Low-Dose Group (n=52)	Standard-Dose Group (n=52)	p-value
Mean age (years)	5.48 ± 2.36	5.62 ± 2.29	0.78
Male gender, n (%)	28 (53.85%)	30 (57.69%)	0.69
Mean weight (kg)	17.86 ± 3.42	18.22 ± 3.18	0.54
Mean respiratory rate (breaths/min)	38.47 ± 5.26	39.12 ± 4.91	0.46
Mean temperature (°C)	38.12 ± 0.64	38.24 ± 0.69	0.38
Mean CRP (mg/L)	12.84 ± 4.23	13.26 ± 4.11	0.57

Table 2: Comparison of Clinical Outcomes Between Study Groups

Clinical Parameter	Low-Dose Group (n=52)	Standard-Dose Group (n=52)	p-value
Clinical cure rate, n (%)	49 (94.23%)	50 (96.15%)	0.65
Treatment failure, n (%)	3 (5.77%)	2 (3.85%)	0.65
Mean duration of fever resolution (days)	2.43 ± 0.94	2.24 ± 0.86	0.28
Mean duration of cough resolution (days)	4.37 ± 1.21	4.16 ± 1.09	0.41

Table 3: Adverse Events Observed During the Study

Adverse Event	Low-Dose Group (n=52)	Standard-Dose Group (n=52)	p-value
Diarrhea, n (%)	4 (7.69%)	5 (9.62%)	0.72
Vomiting, n (%)	3 (5.77%)	2 (3.85%)	0.65
Rash, n (%)	1 (1.92%)	1 (1.92%)	1.00
Total adverse events, n (%)	8 (15.38%)	8 (15.38%)	1.00

Table 4: Comparison of Laboratory and Radiological Response

Parameter	Low-Dose Group (n=52)	Standard-Dose Group (n=52)	p-value
Mean CRP at baseline (mg/L)	12.84 ± 4.23	13.26 ± 4.11	0.57
Mean CRP at Day 7 (mg/L)	5.16 ± 2.07	4.92 ± 2.14	0.49
Mean CRP reduction (%)	59.82%	62.91%	0.33
Radiological improvement, n (%)	47 (90.38%)	48 (92.31%)	0.71

Table 5: Hospitalization and Follow-up Outcomes

Parameter	Low-Dose Group (n=52)	Standard-Dose Group (n=52)	p-value
Hospitalization required, n (%)	2 (3.85%)	1 (1.92%)	0.56
Relapse within 7 days, n (%)	1 (1.92%)	0 (0.00%)	0.31
Overall treatment success, n (%)	49 (94.23%)	50 (96.15%)	0.65

DISCUSSION

Our trial showed clinical cure by Day 7 of 94.23% (low-dose) vs 96.15% (standard-dose) with similar failure rates (5.77% vs 3.85%). This pattern closely mirrors the non-inferiority signal reported by Bielicki et al. in CAP-IT, where lower daily doses performed comparably to higher doses for outpatient pediatric CAP. In other words, our high absolute cure proportions fit squarely within their dose-flexibility framework.^[8]

Symptom trajectories were likewise comparable between groups in our study—fever resolution 2.43 ± 0.94 vs 2.24 ± 0.86 days and cough resolution 4.37 ± 1.21 vs 4.16 ± 1.09 days—paralleling Pernica et al. who found that shorter, pragmatic regimens did not prolong symptoms among ambulatory children. The small numerical edge for fever in the standard-dose arm in our data was clinically trivial, echoing their conclusions.^[9]

Regarding dosing rationale, our finding that 30 mg/kg/day achieved outcomes comparable to 90 mg/kg/day resonates with stewardship-minded interpretations of guidance synthesized by Bradley et al., who emphasize matching dose intensity to local resistance risk. In settings with lower pneumococcal non-susceptibility, our results support a conservative dose without compromising cure.^[10]

Our baseline imaging to exclude complicated disease and the subsequent clinical cure ≥94% with radiographic improvement ~91% align with Harris et al., who place amoxicillin first-line for uncomplicated cases and caution against routine imaging beyond targeted indications. The strong clinical response in both arms of our trial is consistent with that pragmatic approach.^[11]

Inflammatory response tracked well in our cohort: CRP fell ~60% by Day 7 (59.82% vs 62.91%) with no between-group difference. This use of CRP mainly as a monitor of improvement rather than a dosing guide is congruent with Korppi et al., who showed CRP is helpful for follow-up but limited for etiologic discrimination in pediatric pneumonia.^[12]

Radiology outcomes, improvement in 90.38% vs 92.31%—and our choice to re-image only when clinically indicated match the synthesis by Swingle et al., who noted chest radiographs do not reliably distinguish viral from bacterial disease and have

limited value for routine follow-up when children are improving.^[13]

Similarly, our minimal use of routine post-treatment radiographs and the very low relapse (1.92% vs 0%) reflect the low diagnostic yield described by Heckerling et al. for repeat imaging in recovering outpatients. Clinical trajectories in our dataset supported watchful clinical follow-up rather than imaging-driven decisions.^[14]

Tolerability was virtually identical across doses in our trial, any adverse event 15.38% in each arm; diarrhea 7.69% vs 9.62%; vomiting 5.77% vs 3.85%; rash 1.92% vs 1.92%—which accords with the pediatric synthesis by Gillies et al., who reported modest diarrhea rates with amoxicillin monotherapy and higher rates with clavulanate-containing regimens. Our data therefore suggest that dose did not materially change tolerability in uncomplicated CAP.^[15]

Finally, our high cure, low relapse, and rapid defervescence at a lower total daily dose align conceptually with the short-course effectiveness demonstrated by Awasthi et al. in large LMIC trials, where 3-day amoxicillin was non-inferior to 5 days for non-severe CAP. Although our study compared dose rather than duration, both bodies of evidence converge on the principle that many children with uncomplicated CAP recover reliably with leaner antibiotic strategies when selection criteria and follow-up are sound.^[16]

CONCLUSION

This pragmatic clinical trial demonstrated that low-dose amoxicillin (30 mg/kg/day) is as effective and safe as the standard-dose regimen (90 mg/kg/day) for treating uncomplicated pediatric community-acquired pneumonia. Both dosing strategies achieved comparable clinical cure rates, symptom resolution, and adverse-event profiles. These findings suggest that a lower amoxicillin dose can be a reliable, cost-effective, and stewardship-friendly option for non-severe CAP in children, particularly in settings with low pneumococcal resistance.

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