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# Evaluation of Oral Corticosteroids in Infants with Acute Bronchiolitis: A Quasi-Experimental Study

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## ABSTRACT

Acute bronchiolitis is a major cause of hospitalization in infants and young children, most commonly caused by respiratory syncytial virus (RSV). Despite high spontaneous recovery rates, corticosteroids are frequently used, though their efficacy remains uncertain. **Objective:** To assess the short-term clinical efficacy of oral corticosteroids compared to placebo in infants with acute bronchiolitis. **Methods:** This quasi-experimental study was conducted at the Department of Pediatrics, Qazi Hussain Ahmad Medical Complex, Nowshera. A total of 234 children aged 3 months to 2 years with clinically diagnosed bronchiolitis were enrolled. Participants were allocated to receive either oral prednisolone (1 mg/kg/dose) or placebo twice daily for three days, alongside standard supportive care, including inhaled salbutamol. A blinded examiner assessed treatment response on day 3 using a validated respiratory distress score. Clinical improvement was defined as a reduction of more than two points in the score. **Results:** Clinical improvement was observed in 97.4% of the corticosteroid group and 94.9% of the placebo group. The difference was not statistically significant (p=0.308). Subgroup analyses based on gender, maternal education, socioeconomic status, and maternal occupation showed no significant impact on treatment outcomes. **Conclusions:** Oral corticosteroids did not significantly improve clinical outcomes compared to placebo in infants with mild to moderate bronchiolitis. Given the high rate of natural recovery and the potential for adverse effects, routine corticosteroid use is not recommended. Further research is needed to identify specific subgroups that may benefit from targeted steroid therapy.

## INTRODUCTION

Acute bronchiolitis is a leading cause of lower respiratory tract infections in infants and young children, primarily resulting from inflammation and obstruction of the bronchioles. It most commonly affects children under two years of age and remains a major cause of pediatric hospitalization worldwide [1]. The disease typically presents with cough, wheezing, tachypnea (rapid breathing), and chest retractions (inward movement of chest muscles during breathing), which may progress to respiratory distress in severe cases. While many children recover spontaneously with supportive care, a subset may require hospitalization and even intensive care support in resource-limited settings [2, 3]. Respiratory syncytial virus (RSV) is the most frequently implicated pathogen, accounting for approximately 30–70% of bronchiolitis cases [4]. Other causative agents include parainfluenza

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viruses, influenza A and B, adenovirus, rhinovirus, coronavirus, and human metapneumovirus. These infections typically peak in colder seasons, placing a significant burden on healthcare systems, especially during winter months [5]. Inflammation in bronchiolitis is predominantly neutrophilic and can lead to epithelial damage and airway hyper-responsiveness, predisposing some infants to chronic wheezing and asthma later in life [6, 7]. The mainstay of bronchiolitis management remains supportive care, including hydration, oxygen therapy, and monitoring. However, interventions such as bronchodilators and corticosteroids have been frequently used in practice due to their effectiveness in conditions like asthma and croup [1]. Corticosteroids, in particular, are known for their anti-inflammatory effects, including the ability to reduce mucosal edema and limit immune-mediated tissue injury [8]. Despite widespread use, the clinical efficacy of corticosteroids in bronchiolitis remains controversial. While some randomized trials and observational studies have reported modest improvements in respiratory symptoms and hospital stay duration, many others have failed to demonstrate any significant difference when compared with placebo. This inconsistency in outcomes may reflect the heterogeneity of bronchiolitis in terms of viral etiology, host immune response, and disease severity. Consequently, international guidelines, including those from the American Academy of Pediatrics, advise against routine corticosteroid use in typical bronchiolitis cases [9]. In the South Asian region, and particularly within Pakistan, the existing evidence base on this subject remains limited [10]. Although corticosteroids continue to be prescribed for bronchiolitis in many local hospitals, robust local data evaluating their impact are scarce. A study from Pakistan by Ameen, Salahuddin, and Irfan (2025 found no clinical benefit from steroid use in bronchiolitis, highlighting the need for context-specific studies in neighboring populations [11]. To the best of our knowledge, no quasi-experimental study in Pakistan has directly compared oral corticosteroids with placebo in infants diagnosed with bronchiolitis, making this investigation both novel and necessary.

This study aimed to evaluate the short-term clinical efficacy of oral corticosteroids (prednisolone) in infants with mild to moderate bronchiolitis, using a standardized respiratory distress score to assess treatment response. Also, to examine whether demographic or socioeconomic factors influenced treatment outcomes. In addition, to generate local data that could inform pediatric treatment practices in Pakistan, especially in resource-constrained settings, where corticosteroids are often used without definitive guidance.

## METHODS

This quasi-experimental study was conducted in the Department of Pediatrics at Qazi Hussain Ahmad Medical Complex (QHAMC), Nowshera, from October 2024 to March 2025. The study aimed to evaluate and compare the clinical efficacy of oral corticosteroids versus placebo in children diagnosed with acute bronchiolitis. The study was approved by the Institutional Ethical Review Board (IERB) of QHAMC (Ref. No. 473/IERB/NMC) and by the Research Evaluation Unit (REU) of the College of Physicians and Surgeons Pakistan (Ref. No. CPSP/REU/PED-2022-305-6857). Informed, written consent was obtained from parents or legal guardians of all participants before enrolment. The study was conducted in full accordance with the ethical principles outlined in the Declaration of Helsinki (2013 revision), ensuring the rights, safety, and well-being of the Pediatric participants. Using non-probability consecutive sampling, 234 children aged 3 months to 2 years with clinical features of acute bronchiolitis were enrolled. Patients were non-randomly assigned to two groups based on a predefined allocation protocol maintained by the attending clinical team. The steroid group received oral prednisolone (1 mg/kg/dose) twice daily for 3 days. Placebo group: received a matched placebo solution with the same schedule. Both groups also received standard supportive care, including nebulized salbutamol, hydration, and oxygen therapy if required. Clinical efficacy was defined as a reduction of more than two points in the standardized Respiratory Distress Score after three days of treatment. This composite score (0–9) assessed three parameters: respiratory rate, wheezing, and use of accessory muscles. A reduction of ≤2 points was classified as no improvement. Inclusion Criteria were age 3 months to 2 years. Clinical diagnosis of bronchiolitis (cough, tachypnea, wheezing or crackles, chest retractions). Respiratory rate >60/min (for <12 months) or >50/min (for >12 months) and $SpO_2$ <90% on room air. Exclusion Criteria were suspected or confirmed asthma. Bacterial pneumonia. Illness duration >7 days. Requirement for ICU or ventilatory support. Prematurity or chronic cardiopulmonary/neurological disorders and corticosteroid contraindications. At baseline, demographic details and clinical parameters were recorded. A single, trained pediatrician blinded to treatment allocation assessed respiratory scores on Day 1 and Day 3 to reduce inter-observer variability and bias. Sample size was estimated using an online calculator (UBC Statistics). Based on prior data showing clinical improvement of 99% in the steroid and 91% in the placebo groups [12], at a 95% confidence level, 80% power, and 5% margin of error, the required sample was 234 (117 in each group). The following formula was used:

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$n = [(Z\alpha/2 + Z\beta)^2 \times (p1(1-p1) + p2(1-p2))] / (p1-p2)^2$. Where: n = required sample size per group, Zα/2 = Z-value for desired confidence level (e.g., 1.96 for 95%), Zβ = Z-value for desired power (e.g., 0.84 for 80%), p1 = expected proportion in group 1 (e.g., steroid group), p2 = expected proportion in group 2 (e.g., placebo group) and (p1 - p2) = effect size (difference between two proportions). p1 = 0.99 and p2 = 0.91, Zα/2 = 1.96, Zβ = 0.84. $n = [(1.96 + 0.84)^2 \times (0.99 \times 0.01 + 0.91 \times 0.09)] / (0.99 - 0.91)^2$ n = required sample size per group = 117. Total sample = 234 participants. All data were analyzed using SPSS version 25.0. The Shapiro-Wilk test was used to assess normality for quantitative variables (age, weight, hospital stay). As the data were not normally distributed, results were reported as medians (IQRs) and analyzed using non-parametric tests. Descriptive statistics were applied to demographic data. Clinical efficacy (primary outcome) was compared between groups using the Chi-square test, and Fisher's Exact Test was used when expected counts were <5. Cramer's V was calculated for the effect size. A p-value <0.05 was considered statistically significant.

## RESULTS

A total of 234 children aged 3 months to 2 years with clinically diagnosed bronchiolitis were included in this quasi-experimental study. Participants were equally assigned to either the corticosteroid group (n=117) or the placebo group (n=117). The overall cohort included slightly more female (53%) than male (47%). Most mothers had either an elementary (27.8%) or a graduate (25.6%) education. Regarding economic status, 36.3% were classified as well-off, 35.9% as middle-income, and 27.8% as poor. The majority of participants lived in rural areas (53.8%). In terms of maternal occupation, 35.5% were housewives, 34.6% manual workers, and 29.9% were employed in executive roles (Table 1).

**Table 1:** Descriptive Statistics of Categorical Variables (n=234)

| Variables | Category | n (%) |
|---|---|---|
| Study Group | Corticosteroid | 117 (50.0%) |
| | Placebo | 117 (50.0%) |
| Gender | Female | 124 (53.0%) |
| | Male | 110 (47.0%) |
| Mother's Education | Elementary | 65 (27.8%) |
| | Graduate | 60 (25.6%) |
| | Highly Educated | 55 (23.5%) |
| | Uneducated | 54 (23.1%) |
| Economic Status | Well-off | 85 (36.3%) |
| | Middle-income | 84 (35.9%) |
| | Poor | 65 (27.8%) |
| Living Area | Rural | 126 (53.8%) |
| | Urban | 108 (46.2%) |
| Maternal Profession | Housewife | 83 (35.5%) |
| | Manual Worker | 81 (34.6%) |
| | Executive | 70 (29.9%) |
| Treatment Outcome | Improved | 225 (96.2%) |
| | Not Improved | 9 (3.8%) |

The median age of participants was 12 months (IQR=11), and mean age was 12.43 ± 6.22 months. Median weight was 9.8 kg (IQR=4.9) and mean weight was 9.94 ± 2.88 kg. Median duration of hospital stay was 2 days (IQR=0.0), with a mean of 2.09 ± 0.46 days. All variables were non-normally distributed based on the Shapiro-Wilk test (Table 2).

**Table 2:** Descriptive Statistics of Quantitative Variables (n=234)

| Variable | Median (IQR) | Mean ± SD |
|---|---|---|
| Age (Months) | 12 (11) | 12.43 ± 6.22 |
| Weight (kg) | 9.8 (4.9) | 9.94 ± 2.88 |
| Hospital Stay (Days) | 2.0 (0.0) | 2.09 ± 0.46 |

Clinical improvement was defined as a >2-point reduction in the standardized respiratory distress score by Day 3. A total of 225 children (96.2%) met this criterion. The corticosteroid group showed an improvement rate of 97.4%, compared to 94.9% in the placebo group. However, this difference was not statistically significant ($\chi^2 = 1.04$, p=0.308). Fisher's Exact Test confirmed the non-significance due to small cell counts, and the effect size (Cramer's V=0.067) indicated a very weak association between treatment and outcome. Subgroup comparisons were conducted across gender, maternal education, economic status, residence, and maternal occupation. While some numeric differences were noted, none were statistically significant (Table 3).

**Table 3:** Subgroup Comparison of Treatment Efficacy (n=234)

| Subgroups | Category | Improved n (%) | Not Improved n (%) | Chi-square (p-value) |
|---|---|---|---|---|
| Overall | Corticosteroid | 114 (97.4%) | 3 (2.6%) | 1.04 (p=0.308) |
| | Placebo | 111 (94.9%) | 6 (5.1%) | |
| Female | Corticosteroid | 58 (96.7%) | 2 (3.3%) | 0.004 (p=0.948) |
| | Placebo | 62 (96.9%) | 2 (3.1%) | |
| Male | Corticosteroid | 56 (98.2%) | 1 (1.8%) | 2.124 (p=0.145) |
| | Placebo | 49 (92.5%) | 4 (7.5%) | |
| Mother's Education: Elementary | Corticosteroid | 32 (100.0%) | 0 (0.0%) | 3.050 (p=0.081) |
| | Placebo | 30 (90.9%) | 3 (9.1%) | |
| Graduate | Corticosteroid | 32 (97.0%) | 1 (3.0%) | 0.021 (p=0.885) |
| | Placebo | 26 (96.3%) | 1 (3.7%) | |
| Highly Educated | Corticosteroid | 23 (92.0%) | 2 (8.0%) | 0.576 (p=0.448) |
| | Placebo | 29 (96.7%) | 1 (3.3%) | |
| Uneducated | Corticosteroid | 27 (100.0%) | 0 (0.0%) | 1.019 (p=0.313) |
| | Placebo | 26 (96.3%) | 1 (3.7%) | |
| Economic Status: Poor | Corticosteroid | 43 (97.7%) | 1 (2.3%) | 0.485 (p=0.486) |
| | Placebo | 21 (100.0%) | 0 (0.0%) | |
| Middle-income | Corticosteroid | 28 (100.0%) | 0 (0.0%) | 1.024 (p=0.311) |
| | Placebo | 54 (96.4%) | 2 (3.6%) | |

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| | | | | |
|---|---|---|---|---|
| Well-off | Corticosteroid | 43 (95.6%) | 2 (4.4%) | 0.996 (p=0.318) |
| | Placebo | 36 (90.0%) | 4 (10.0%) | |
| Living Area: Rural | Corticosteroid | 66 (98.5%) | 1 (1.5%) | 1.317 (p=0.251) |
| | Placebo | 56 (94.9%) | 3 (5.1%) | |
| Urban | Corticosteroid | 48 (96.0%) | 2 (4.0%) | 0.084 (p=0.772) |
| | Placebo | 55 (94.8%) | 3 (5.2%) | |
| Maternal Profession: Executive | Corticosteroid | 43 (97.7%) | 1 (2.3%) | 1.170 (p=0.279) |
| | Placebo | 24 (92.3%) | 2 (7.7%) | |
| Housewife | Corticosteroid | 34 (97.1%) | 1 (2.9%) | 0.508 (p=0.476) |
| | Placebo | 45 (93.8%) | 3 (6.3%) | |
| Manual Worker | Corticosteroid | 37 (97.4%) | 1 (2.6%) | 0.008 (p=0.929) |
| | Placebo | 42 (97.7%) | 1 (2.3%) | |

The finding illustrates the proportion of children who improved in both groups. While both arms demonstrated high efficacy, the steroid group had fewer non-responders (2.6%) than the placebo group (5.1%). Though not statistically significant, this trend suggests a possible clinical benefit in some subgroups. The majority in both groups improved, with a slightly higher number of non-improved cases in the Placebo group (Figure 1).

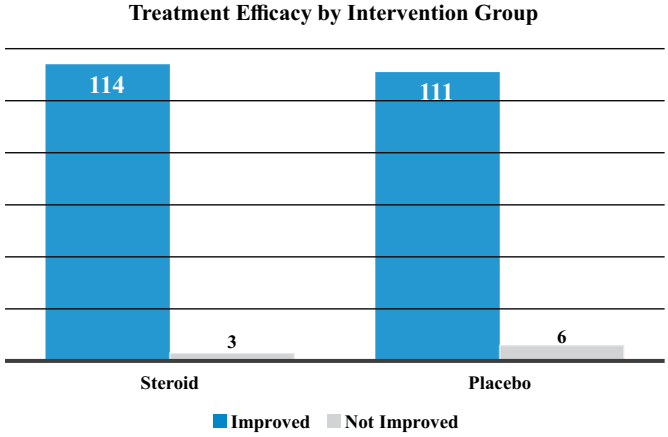


**Figure 1:** Improvement Versus No Improvement Across the Steroid and Placebo Groups

## DISCUSSION

This quasi-experimental study evaluated the short-term clinical efficacy of oral corticosteroids in infants with acute bronchiolitis. Among the 234 enrolled participants, both treatment groups showed high rates of clinical improvement by Day 3, with no statistically significant difference between the corticosteroid (97.4%) and placebo (94.9%) groups (p=0.308). Subgroup analyses across gender, maternal education, economic status, residential status, and maternal profession similarly showed no significant variation in outcomes. These findings were consistent with international clinical guidelines, such as those of the American Academy of Pediatrics, which recommend against the routine use of corticosteroids in bronchiolitis due to lack of proven benefit in most cases [12]. Multicenter trials and meta-analyses support this recommendation, highlighting the self-limiting nature of bronchiolitis and the high rate of spontaneous clinical resolution without pharmacological intervention [13-15]. Regionally, there was a noticeable scarcity of robust clinical studies on this topic in the Pakistani setting. However, limited data from tertiary care centers in South Asia mirror our results. For instance, Hasan et al. from Bangladesh observed widespread steroid use in pediatric bronchiolitis with no significant clinical advantage [16]. To our knowledge, this was among the first quasi-experimental studies in Pakistan specifically comparing oral corticosteroids and placebo for bronchiolitis in a controlled setting, thereby contributing much-needed local evidence. Internationally, some studies have suggested that corticosteroids may have a selective benefit in particular patient subgroups. Gelbart et al. found that in children with severe bronchiolitis requiring ventilation, corticosteroids may reduce the duration of respiratory support [17]. Others suggest a possible benefit in children with rhinovirus-associated bronchiolitis or first-time wheezers older than six months [18, 19]. However, these findings are not universally applicable and require more precise patient stratification. Our study reinforces the understanding that bronchiolitis is a clinically heterogeneous illness. Unlike asthma or croup, which respond predictably to anti-inflammatory therapy, bronchiolitis may involve variable viral triggers, age-related immune responses, and differing inflammatory profiles [20, 21]. Therefore, a uniform corticosteroid approach may not be justified for the general pediatric population. Importantly, the safety profile of corticosteroids must be carefully considered. Even short-term use may increase the risk of hyperglycemia, secondary infection, or other adverse effects [22]. Although our study did not record significant adverse events, the absence of added benefit makes such risks less acceptable in routine practice. Strengths of this study include a relatively large sample size, clear inclusion/exclusion criteria, blinded outcome assessment, and the use of a standardized clinical scoring system. This enhances the reliability and reproducibility of findings.

## CONCLUSIONS

Oral corticosteroids showed no statistically significant benefit over placebo in infants with mild to moderate bronchiolitis over a short-term period. While both treatment groups demonstrated high rates of clinical improvement, the findings suggest that routine corticosteroid use offers limited additional advantage and should be approached cautiously. Given the self-limiting nature of bronchiolitis and the potential for adverse effects, corticosteroids should not be routinely prescribed in such cases.

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## Authors Contribution

Conceptualization: AR
Methodology: MUS, GMZ, AS
Formal analysis: AR, IK, SN
Writing review and editing: AR, IK, GMZ, AS

All authors have read and agreed to the published version of the manuscript

## Conflicts of Interest

All the authors declare no conflict of interest.

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