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Effect of Addition of Oral Montelukast to Conventional Therapy in Post-Bronchiolitis Reactive Airway

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Abstract

Introduction: Respiratory syncytial virus (RSV) bronchiolitis in infants frequently triggers post-bronchiolitis reactive airway disease (RAD), driven by cysteinyl leukotriene (CysLT) release and persistent airway inflammation, leading to substantial clinical and economic burden in resource-limited settings.

Objectives: To assess the clinical efficacy of oral montelukast added to conventional treatment compared with conventional treatment alone in improving symptom-free days and alleviating post-bronchiolitis reactive airway symptoms (daytime cough, nighttime cough, wheeze, hurried breathing, and activity limitation) over a 28-day follow-up.

Methods: A prospective, open-label comparative study was carried out in the Department of Pediatrics, Princess Durru Shehvar Hospital, Hyderabad, across two winter seasons (June 2007 to May 2009). Sixty hospitalized infants and young children aged 3 to 36 months with moderate-to-severe bronchiolitis were enrolled. Thirty children received oral montelukast (4 mg/day chewable tablet or sachet) for 28 days following clinical stabilization alongside conventional care, while 30 received conventional treatment alone. Daily symptom scores were recorded on standardized parental diary cards. Outcomes were analyzed using the Mann-Whitney U test and paired t-tests.

Results: Infants receiving montelukast exhibited a significantly higher median percentage of symptom-free days and nights (54% vs. 12%, $z = -6.40$, $p < 0.0001$). Median symptomatic days were significantly lower in the montelukast group for daytime cough (10 vs. 14 days), nighttime cough (7 vs. 16 days), wheeze (8 vs. 16 days), hurried breathing (6 vs. 10 days), and limitation of activity (6 vs. 10 days; all $p < 0.0001$).

Conclusion: Addition of oral montelukast to conventional therapy significantly increases symptom-free days and attenuates recurrent respiratory morbidity in post-bronchiolitis reactive airway disease, offering an effective and affordable oral controller option.

Keywords: *Bronchiolitis, Cysteinyl leukotrienes, Montelukast, Reactive airway disease, Respiratory syncytial virus, Wheezing.*

Introduction

Respiratory syncytial virus (RSV) is the foremost etiology of acute bronchiolitis in infants and represents a formidable global pediatric public health burden. A pronounced peak in incidence is observed during winter months, predominantly affecting infants between 2 and 6 months of age, with nearly all children experiencing natural infection before two years of age [1]. Hospitalization rates for infant bronchiolitis have surged over recent decades, now accounting for one in six pediatric admissions during infancy, with approximately 50% of infant lower respiratory tract hospitalizations attributed directly to RSV [2].

Acute bronchiolitis is frequently followed by reactive airway disease (RAD), manifesting clinically as recurrent episodes of wheezing, chronic cough, tachypnea (hurried breathing), and limitation of physical activity [3]. These debilitating manifestations often persist for weeks, months, or years after initial discharge. Prospective observational investigations indicate that post-bronchiolitis airway hyperreactivity constitutes a prominent precursor to childhood asthmatic syndromes, particularly in young individuals [4].

In the pathophysiology of RSV-mediated bronchiolitis, cysteinyl leukotrienes (CysLTs: LTC4, LTD4, and LTE4) are rapidly synthesized and released from membrane phospholipids by activated inflammatory leukocytes. CysLTs induce mucosal hyperperfusion, microvascular hyperpermeability, submucosal edema, smooth muscle bronchoconstriction, impairment of mucociliary clearance, and marked hypersecretion of mucus, producing small airway luminal obstruction [5-8]. Consequently, pharmacological antagonism of cysteinyl leukotrienes represents a rational therapeutic strategy to mitigate both acute mucosal damage and chronic airway remodeling [5,8].

Conventional medical management of post-bronchiolitis reactive airway disease primarily entails humidified oxygen supplementation, upright positioning (elevating head and trunk to 30 to 40 degrees), maintenance of fluid and electrolyte equilibrium, selective short-acting inhaled beta-2 agonists (salbutamol) with or without ipratropium bromide, and ventilatory support when clinically indicated. However, established evidence-based pharmacological interventions targeting chronic post-bronchiolitis recurrent wheeze remain scarce. Routine bronchodilator therapy carries questionable long-term efficacy and risks tachyphylaxis. Corticosteroids, administered either systemically or via inhalation, demonstrate negligible clinical alteration of long-term post-bronchiolitis morbidity while posing potential risks of linear growth deceleration in prepubertal children upon prolonged administration [9-11].

Montelukast is a selective, potent oral cysteinyl leukotriene receptor antagonist (LTRA) that dampens the inflammatory cascade by inhibiting proinflammatory cytokine elaboration, mucosal infiltration of neutrophils, eosinophils, and mast cells, and end-organ leukotriene signaling [12]. Possessing high oral bioavailability and a favorable pediatric safety profile, montelukast circumvents the substantial technical compliance barriers and nebulization challenges associated with multiple-daily-dose inhaled corticosteroid regimens [13,14]. Given that lower-middle-class urban families often encounter severe financial and logistical obstacles maintaining chronic inhaler devices or home nebulizers, evaluating a cost-effective, easily administered once-daily oral tablet or sachet formulation is of immediate clinical relevance. Hence, this clinical investigation was conducted to determine the therapeutic impact of oral montelukast on symptom-free days and clinical resolution in post-bronchiolitis reactive airway disease.

Methods

Study Design and Setting

This study was conceptualized and conducted as a prospective, open-label, comparative parallel-group trial in the Department of Pediatrics at Princess Durru Shehvar Children's & General Hospital, Purani Haveli, Hyderabad, India. The patient recruitment spanned two successive winter epidemics over a 24-month timeframe from June 2007 to May 2009.

Ethical Considerations

The experimental protocol received formal clearance from the Institutional Ethics Committee. Fully informed written consent was voluntarily secured in the regional language from the parents or legal guardians of all participating children prior to recruitment, following thorough counseling regarding the natural history of bronchiolitis and the proposed intervention.

Eligibility Criteria

Eligible participants comprised hospitalized children aged 3 to 36 months presenting with an acute episode of moderate-to-severe bronchiolitis. Clinical diagnosis was established by the resident pediatrics & consultant pediatricians based on acute coryza, cough, expiratory wheezing, tachypnea, chest retractions, and supportive hyperinflation findings on chest radiography (Table 1). Routine RSV antigen detection kits could not be systematically deployed due to financial constraints and regional diagnostic supply limitations.

Exclusion criteria were: (a) prior therapy with inhaled corticosteroids (ICS) within four weeks preceding enrollment; (b) gestational age < 36 completed weeks; (c) preexisting chronic underlying cardiopulmonary, genetic, or neuromuscular diseases (e.g., bronchopulmonary dysplasia, cystic fibrosis, congenital heart anomalies); (d) children whose coughing and wheezing deteriorated to require rescue systemic or inhaled corticosteroids; and (e) premature discontinuation of study protocol.

Table 1: Clinical Assessment of Bronchiolitis Severity*

Clinical Parameter	Mild	Moderate	Severe
Respiratory Rate	Normal to slightly increased	Increased	Markedly increased (>70/min in <6 mo; >60/min in 6-12 mo; >40/min in >12 mo)
Respiratory Effort	Mild intercostal/ subcostal retractions	Moderate retractions, nasal flaring, tracheal tug	Marked retractions, nasal flaring, audible grunting
Oxygen Saturation	>95% in ambient room air	90% - 95% in room air	<90% in room air (refractory or requiring O2)
Feeding Ability	Normal to mildly decreased	50% - 75% of normal intake	<50% of baseline feeds; unable to suck/ swallow
Apneic Episodes	None reported	Infrequent, brief self-limiting episodes	Recurrent, prolonged, or worsening apnea

***Footnote:** Adapted from Princess Margaret Hospital Clinical Practice Guidelines for Bronchiolitis [36]. All patients enrolled in the trial exhibited moderate-to-severe disease criteria.

Intervention and Treatment Regimens

All enrolled patients received standard acute inpatient supportive therapy adhering to departmental guidelines. Following stabilization of acute respiratory distress (typically on inpatient hospital day 2 or 3), patients whose parents consented to the intervention were assigned to the active treatment group (n = 30), receiving oral montelukast at an age-appropriate dose of 4 mg once daily (chewable tablets or oral granules/sachets administered in evening feeds) for 28 consecutive days in addition to conventional therapy. The remaining eligible cohort (n = 30) received conventional symptomatic treatment alone without montelukast.

Compliance and therapeutic adherence were actively supervised through regular scheduled outpatient visits and weekly structured telephone follow-ups, verified objectively by empty blister sachet reconciliation at day 28.

Outcome Measures and Symptom Assessment

Parents were issued validated, standardized daily symptom diary cards and comprehensively instructed to record daily occurrences (binary: present [tick] / absent [cross]) across five clinical variables: (1) daytime cough, (2) nighttime cough, (3) wheeze, (4) hurried breathing (rapid respiration), and (5) limitation of normal infant play and physical activity. The primary clinical efficacy outcome was defined as the proportion of 24-hour symptom-free days and nights over the 28-day surveillance window (zero symptoms across all five domains). Secondary endpoints comprised median symptom duration days for each individual respiratory variable.

Statistical Analysis

Descriptive baseline demographics were summarized using frequencies and proportions. Continuous clinical outcome measures and ranked symptom scores between the two cohorts were subjected to comparative analysis using paired Student's t-test and the non-parametric Mann-Whitney U test. Standard z-scores, one-tailed p-values, and two-tailed p-values were computed. Two-tailed p-values < 0.05 were regarded as statistically significant.

Results

A total of 60 hospitalized children meeting eligibility criteria completed the full 28-day surveillance period without any dropouts or exclusions for requiring rescue corticosteroid therapy. Baseline demographic profiles, including age distribution, gender allocation, and duration of hospital stay, were balanced across both arms (Table 2). Most enrolled infants (75.0%, n = 45) were aged <= 6 months, reflecting the typical peak epidemiological distribution of acute viral bronchiolitis. Males predominated in both cohorts (70.0% in the montelukast arm, 66.7% in the control arm).

Statistical non-parametric comparison utilizing the Mann-Whitney U test demonstrated a highly significant difference in overall symptom distribution between the two cohorts ($z = -6.40$, $p < 0.0001$; Table 3). The active montelukast cohort achieved a median percentage of symptom-free days and nights of 54%, whereas the control group receiving conventional therapy alone achieved a median of only 12% symptom-free days over the 28-day period (Figure 1).

Table 2: Baseline Socio-Demographic and Clinical Characteristics of Study Cohorts*

Parameter	Montelukast + Conventional (n = 30)	Conventional Alone (n = 30)	Statistical Significance
Age Distribution (months)			
0 - 6	24 (80.0%)	21 (70.0%)	p > 0.05†
6 - 12	5 (16.7%)	8 (26.7%)	p > 0.05†
12 - 18	0 (0.0%)	0 (0.0%)	-
18 - 24	1 (3.3%)	1 (3.3%)	p > 0.05†
24 - 36	0 (0.0%)	0 (0.0%)	-
Gender Distribution			
Male	21 (70.0%)	20 (66.7%)	p > 0.05†
Female	9 (30.0%)	10 (33.3%)	p > 0.05†
Duration of Hospital Stay (days)			
1 - 3	5 (16.7%)	17 (56.7%)	p < 0.05‡
3 - 5	25 (83.3%)	13 (43.3%)	p < 0.05‡

***Footnote:** Values are expressed as frequency (percentage). †Chi-square test revealed no statistically significant differences in age or sex distribution between arms. ‡Hospitalization duration reflected acute inpatient stabilization prior to home diary card recording.

Table 3: Comparison of Diary Card Median Symptom Days Between Present Study and International Literature*

Clinical Variable	Robertson et al. [21] (n=329) Montelukast	Robertson et al. [21] (n=321) Placebo	Present Study (n=30) Montelukast + Conventional	Present Study (n=30) Conventional Alone	Percentage Reduction in Present Study
Daytime cough (median days)	10	11	10	14	64% vs. 50%
Nighttime cough (median days)	9	10	7	16	75% vs. 42%
Wheezing (median days)	4	6	8	16	71% vs. 42%
Hurried breathing (median days)	4	5	6	10	78% vs. 64%
Limitation of activity (median days)	4	6	6	10	78% vs. 64%
Total cumulative symptom days	**37**	**43**	**38**	**69**	**54% vs. 12% (p < 0.0001)†**

***Footnote:** Comparison benchmarks findings from the current clinical trial against international data reported by Robertson et al. [21] (Collin F et al.). †Non-parametric Mann-Whitney U test analysis of cumulative symptom rankings yielded $z = -6.40$, $p < 0.0001$.

Analysis of individual respiratory symptom durations demonstrated marked clinical improvements across all assessed domains in favor of the active montelukast arm:

• Daytime cough: Median symptomatic duration was 10 days in the montelukast group versus 14 days in controls (a 64% symptom-free rate vs. 50% in controls).

• Nighttime cough: Median duration was 7 days in the montelukast group compared to 16 days in controls (75% symptom-free vs. 42%).

• Wheezing: Median duration was 8 days with montelukast compared to 16 days in controls (71% symptom-free vs. 42%).

• Hurried breathing: Median duration was 6 days in the montelukast group compared to 10 days in controls (78% symptom-free vs. 64%).

• Limitation of activity: Median duration was 6 days in the montelukast group versus 10 days in controls (78% symptom-free vs. 64%).

Cumulative overall median symptom days across the 28-day period was 38 days in the montelukast cohort versus 69 days in the control group (Figure 2). No adverse pharmacological events or intolerance leading to drug cessation were reported during the 4-week administration.

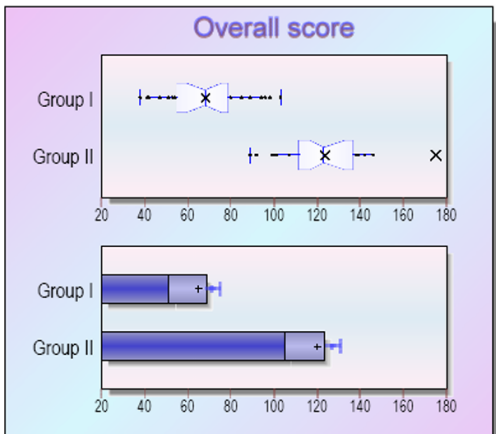


Figure 1: Box-and-whisker plot and bar chart comparing total symptom days and symptom-free proportions between Group I (Montelukast + Conventional Therapy) and Group II (Conventional Therapy Alone) over the 28-day surveillance period. Group I achieved a median of 54% symptom-free days and nights versus 12% in Group II ($z = -6.40$, $p < 0.0001$).

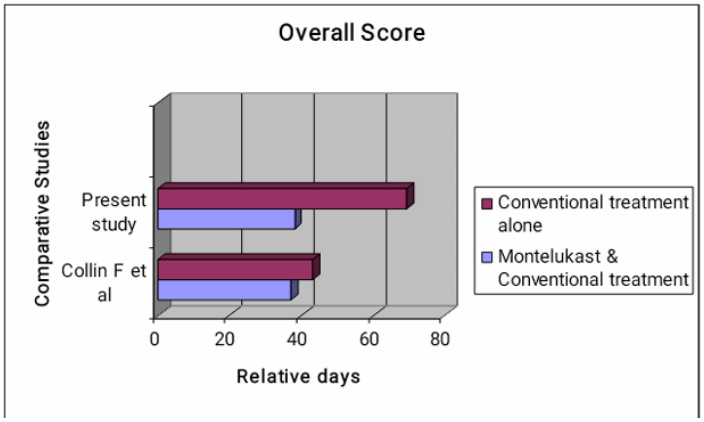


Figure 2: Comparative bar chart of overall median symptom days between the present study and international benchmark data (Robertson et al. / Collin F et al.). Both studies demonstrate substantial reductions in cumulative post-bronchiolitis morbidity following oral leukotriene receptor antagonist therapy.

Discussion

Post-bronchiolitis reactive airway disease imposes an immense socio-emotional and economic strain on pediatric families, characterized by frequent nocturnal waking, recurrent acute outpatient visits, parental absenteeism from work, and impaired infant nutritional thriving [4,15]. This investigation demonstrated that once-daily oral montelukast (4 mg) initiated following clinical stabilization of acute bronchiolitis substantially augmented symptom-free days and nights (54% vs. 12%, $p < 0.0001$), while curbing daytime cough, nocturnal disturbances, wheeze, tachypnea, and play limitations.

Pathophysiologically, RSV directly infects ciliated respiratory epithelium, eliciting cytotoxic mucosal shedding, dense peribronchiolar lymphocytic and neutrophilic infiltration, and intense activation of 5-lipoxygenase pathway mediators [6-8,16-18]. Cysteinyl leukotrienes (LTC4, LTD4, LTE4) amplify post-viral bronchial hyperresponsiveness by promoting prolonged microvascular leakage, submucosal edema, and mucus plugging. In contrast to preschool wheezing phenotypes where steroids frequently exhibit disappointing efficacy or side-effect trade-offs [9,10,19], oral leukotriene receptor antagonism provides targeted receptor blockade without systemic steroid toxicities such as linear growth suppression [10,20].

The findings of our study align with pivotal international trials. In a large multicenter trial by Robertson et al.[21], montelukast administered for post-bronchiolitis intermittent wheeze achieved an overall median symptom score of 37 compared to 43 in placebo recipients, corroborating our observed median of 38 symptom days in active cases versus 69 days in controls. Similarly, Bisgaard et al. (2003) [15] demonstrated a statistically significant increase in symptom-free days (22% vs. 4%, $p = 0.015$) among infants receiving montelukast following acute bronchiolitis. However, in a subsequent 2008 trial by Bisgaard et al. [22], systemic rescue corticosteroids were liberally co-administered, potentially blunting the measurable contrast between study arms due to universal phospholipase enzyme inhibition. In our cohort, corticosteroid therapy was systematically excluded, allowing direct attribution of clinical improvement to leukotriene pathway modulation.

From a socio-economic standpoint, this study holds substantial clinical relevance for developing regions. In lower-middle-class populations, the ongoing recurring expenses of metered-dose inhalers with valved holding chambers or nebulizer maintenance represent insurmountable hurdles. A once-daily chewable tablet or dispersible sachet of montelukast offers reliable, user-friendly adherence, establishing a practical controller option to prevent post-bronchiolitis wheezing relapse.

Study Limitations

Several limitations warrant consideration. The trial was designed as an open-label comparative study without a placebo control arm and lacked formal double-blinding. Outcome measures relied on structured parent-reported diary cards, which carry inherent subjective reporting bias. Furthermore, confirmatory RSV molecular diagnostic kits could not be procured due to economic limitations, and objective physiological measures such as infant pulmonary function testing and bronchial provocation testing were not performed. Further large-scale, double-blind randomized trials with objective lung function correlates are desirable.

Conclusion

The addition of oral montelukast (4 mg daily) to conventional supportive care significantly improves clinical outcomes in infants and young children recovering from acute bronchiolitis. Montelukast markedly expands symptom-free days and nights and expedites the resolution of nocturnal cough, wheezing, hurried breathing, and functional impairment, offering a safe, well-tolerated, and accessible oral therapeutic strategy for post-bronchiolitis reactive airway disease.

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Conflicts of Interest

The authors declare that they have no competing financial, professional, or personal interests that could influence the work reported in this paper.

Author Contributions

Dr Syed Ghazanfar Ali Zafar: Conceptualization, data collection, data analysis, literature review, manuscript drafting, and final approval of the manuscript.

Dr Baswaraj Tandur: Study supervision, critical revision of the manuscript for important intellectual content, and final approval of the manuscript.

Dr Naziya Syed: Helper in Data processing and literature review

Ethics Approval

The study was approved by the Institutional Ethics Committee of Princess Durru Shehvar Pediatric and General Hospital, Hyderabad. Written informed consent was obtained from parents or legal guardians prior to enrollment.

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None.

Data Sharing Statement

De-identified individual participant data will be made available at reasonable request to the corresponding author.

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