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EFFICACY OF ORAL RIBAVIRIN IN OUTCOME OF BRONCHIOLITIS DUE TO RESPIRATORY SYNCYTIAL VIRUS (RSV) IN CHILDREN ON CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) THERAPY

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ABSTRACT

Background: Respiratory syncytial virus (RSV) bronchiolitis is a significant cause of acute respiratory disease in young children, especially those under the need of continuous positive airway pressure (CPAP) support. The possibility of oral ribavirin in the betterment of the outcome in such a high-risk population is a clinically important issue. **Aim:** To assess the effectiveness of oral ribavirin to enhance clinical outcomes in children with RSV bronchiolitis who need support using CPAP. **Methods:** A randomized controlled trial was carried out at the Rawal Medical and Dental Hospital in Islamabad during a period of three months, from 20th December 2025 to 20th March 2026. Four hundred and sixty children aged 1-24 months with confirmed RSV bronchiolitis were recruited and randomized to a ribavirin (n=230) or control group (n=230). The ribavirin group was provided with oral ribavirin (812mg/kg/day) during 5 days and support, and control group was administered to the ribavirin were provided with routine management. The main outcome was the successful treatment, which is the discharge without complications in five days. Secondary outcomes included hospital stay, respiratory complications, need for ventilatory support, and mortality. Statistical analysis was performed with SPSS version 26 and a statistical significance of $p \leq 0.05$. **Results:** Success of treatment was seen in 211 (91.7%) patients with ribavirin group versus 199 (86.5%) patients with the control group though the difference was not statistically significant ($p = 0.072$). Ribavirin was associated with significantly lower rates of retractions (13.9% vs. 26.1%, $p = 0.001$), cyanosis or oxygen requirement (10.4% vs. 29.6%, $p < 0.001$), ventilator support (7.4% vs. 13.0%, $p = 0.045$), and mortality (1.3% vs. 7.0%, $p = 0.002$). Stratified analysis demonstrated much higher treatment success among patients with age >12 months ($p = 0.014$) and male patients ($p = 0.015$). **Conclusion:** Oral ribavirin, in comparison with supportive care alone, did not significantly increase the primary outcome of treatment success, but was linked with significant improvements in respiratory complications, ventilatory support, and mortality. These results indicate that there may be a clinical utility of ribavirin in severe RSV bronchiolitis that is treated with CPAP in children, despite the need of additional multicenter research.

KEYWORDS: Respiratory syncytial virus; bronchiolitis; ribavirin; continuous positive airway pressure; CPAP; treatment success; complications; mortality.

INTRODUCTION:

Acute bronchiolitis refers to inflammation and obstruction of the lower respiratory tract, almost exclusively caused by viral infection in children younger than 2 years.[1] The condition typically begins with symptoms like rhinitis or congestion and cough, which may progress to increasing respiratory distress, characterized by tachypnea, wheezing, and the use of accessory muscles for breathing.[2]The severity of bronchiolitis can vary widely, ranging from mild symptoms that can be managed at home to severe respiratory failure requiring invasive ventilation.[3-4] Despite the existence of clinical guidelines, there remains considerable variation in the care provided to infants admitted to the hospital with bronchiolitis.[5]

Ribavirin, an antiviral medication, has been explored for its potential in treating bronchiolitis, particularly cases caused by Respiratory Syncytial Virus (RSV).[6] The drug works by inhibiting viral RNA synthesis and mRNA capping, which reduces viral replication. This mechanism suggests a potential benefit in reducing the severity and duration of viral infections like RSV bronchiolitis.[7]

Clinical studies on Ribavirin's efficacy in treating bronchiolitis have yielded mixed results. Some research indicates that Ribavirin may offer modest benefits, especially in severe cases or among high-risk populations such as immunocompromised children or those with underlying conditions like congenital heart disease, chronic lung disease, or prematurity. These studies suggest that Ribavirin can reduce the severity of symptoms and shorten hospital stays in these vulnerable groups. However, other studies show minimal or no significant improvement in clinical outcomes for the general pediatric population with RSV bronchiolitis, questioning the broad utility of Ribavirin in this context. [8-9]

Current clinical guidelines, such as those from the American Academy of Pediatrics (AAP), reflect these mixed findings. The AAP does not recommend the routine use of Ribavirin for all children with bronchiolitis, primarily due to the lack of consistent evidence showing significant clinical benefits and the high cost and logistical challenges of administering the drug. Instead, Ribavirin is considered for use in severe cases or specific high-risk patients where the potential benefits might outweigh the drawbacks.[10]

In a trial of ribavirin, after 3 days of therapy, ribavirin produced a greater rate of improvement of analog scores (p = less than or equal to 0.001), lower oxygen requirements (p = 0.01), and higher oxygen saturation (p = 0.01). Respiratory scores and total hospital days did not differ significantly between the groups. Treatment successful occurred in 18 of 20 children (90%) in the ribavirin group versus 22 of 27 children (82%) in the placebo group. No child required assisted ventilation or had an adverse reaction. They concluded that early ribavirin therapy may help to reduce morbidity from respiratory syncytial virus infection in high-risk young children. [11]

Respiratory syncytial virus (RSV) is a leading cause of bronchiolitis in infants, with severe cases often requiring respiratory support such as Continuous Positive Airway Pressure (CPAP). While supportive care remains standard, oral ribavirin—a broad-spectrum antiviral—offers a potentially effective, less invasive, and more accessible treatment option compared to its aerosolized form. However, limited data exist regarding its effectiveness in RSV bronchiolitis patients requiring CPAP. This study aims to determine the frequency of treatment success with oral ribavirin in this high-risk group, providing evidence to guide clinical decision-making and improve outcomes in severe RSV infections.

METHODOLOGY

This study was conducted as a randomized controlled trial (RCT) at Rawal Medical and Dental Hospital, Islamabad, over a duration of three months, from 20th December 2025 to 20th March 2026 after obtaining approval from the institutional Ethical Review Committee and CPSP. A non-probability consecutive sampling technique was employed to recruit participants. The sample size was calculated using the WHO sample size calculator, taking the expected treatment success of ribavirin as 90% compared to 82% in the control group, with a power of 80% and a level of significance of 5%, resulting in a total sample size of 460 patients (230 in each group).

Infants aged 1 month to 24 months, of either gender, admitted with a diagnosis of bronchiolitis confirmed by an unbiased consultant pediatrician, were included in the study. Only those patients who presented within the first three days of illness, required CPAP support, and had confirmed respiratory syncytial virus (RSV) infection based on nasal swab viral serology from NIH Islamabad were enrolled. Children with a history of prematurity, congenital heart disease, bronchopulmonary dysplasia, malnutrition, prior treatment with antibiotics or steroids, or age greater than 24 months were excluded from the study.

After obtaining informed consent from parents or guardians, eligible patients were randomly allocated into two groups. The experimental group (cases) received oral ribavirin in addition to standard supportive care, while the control group received routine management alone. Ribavirin syrup was administered in a formulation of 200 mg/5 ml at a dose of 8–12 mg/kg once daily for five days, under the supervision of a consultant pediatrician who remained blinded to study allocation. Data were collected prospectively using a structured proforma, which included demographic details (age, gender), clinical features, and outcome variables. Patients were followed throughout their hospital stay until discharge or escalation of respiratory support. The primary outcome was treatment success, defined as discharge within five days without development of complications. Secondary outcomes included hospital stay duration and the occurrence of complications such as retractions/respiratory distress, wheezing, cyanosis or oxygen requirement, need for ventilatory support, and mortality. All data were obtained from patient charts, physician notes, nursing records, and discharge summaries. Data analysis was performed using SPSS version 26. Quantitative variables such as age and hospital stay were expressed as mean ± standard deviation (SD), while qualitative variables such as gender, treatment success, and complications were presented as frequencies and percentages. Stratification was performed with respect to age, gender, and duration of illness to control for effect modifiers. Post-stratification, the chi-square test was applied to assess associations between variables and treatment outcomes. A p-value ≤ 0.05 was considered statistically significant.

RESULTS

The mean age of participants was 12.38 ± 6.99 months, with a range of 1 to 24 months, indicating that the study included infants across the full spectrum of early childhood. The mean duration of disease at presentation was 2.50 ± 0.29 days (range: 2–3 days), suggesting that most patients presented early in the course of illness. The average hospital stay was 82.86 ± 24.99 hours, with a wide range from 30 to 167 hours, reflecting variability in disease severity and response to treatment. When categorized, 236 (51.3%) patients were aged ≤12 months, while 224 (48.7%) were older than 12 months, demonstrating a nearly equal age distribution. In terms of gender, 239 (52.0%) patients were male and 221 (48.0%) were female, indicating a balanced representation of both sexes. Overall, the baseline characteristics show a well-distributed and homogeneous study population, which supports the internal validity of the comparative analysis between study groups (Table 1).

Table 1: Baseline Characteristics

Variable	Category	Frequency	Percentage
Age (months)	Mean ± SD	12.38 ± 6.99	—
	Range	1 – 24	—
Duration of Disease (days)	Mean ± SD	2.50 ± 0.29	—
	Range	2 – 3	—
Hospital Stay (hours)	Mean ± SD	82.86 ± 24.99	—
	Range	30 – 167	—
Age Group	≤12 months	236	51.3
	>12 months	224	48.7
Gender	Male	239	52.0
	Female	221	48.0
Total		**460**	**100.0**

Regarding comparison of treatment success between both groups, it was observed in 211 (91.7%) patients in the ribavirin group compared to 199 (86.5%) in the control group. Although the ribavirin group showed a higher success rate, the difference was not statistically significant (p = 0.072). This suggests that while ribavirin may have a clinically favorable effect, it did not demonstrate a statistically significant improvement in the primary outcome (Table 2).

Table 2: Treatment Success

Successful Outcome	Ribavirin	Control	Total	p-value
Yes	211 (91.7%)	199 (86.5%)	410	0.072
No	19 (8.3%)	31 (13.5%)	50	
Total	**230 (100%)**	**230 (100%)**	**460 (100%)**	

Retractions were significantly lower in the ribavirin group (13.9%) compared to the control group (26.1%) (p = 0.001). Similarly, cyanosis or oxygen requirement was markedly reduced in the ribavirin group (10.4%) versus the control group (29.6%) (p < 0.001). The need for ventilator support was also lower in the ribavirin group (7.4%) compared to controls (13.0%) (p = 0.045). Mortality was significantly reduced in the ribavirin group (1.3%) compared to the control group (7.0%) (p = 0.002). These findings indicate that ribavirin significantly reduces complications associated with RSV bronchiolitis (Table 3).

Table 3: Complications

Variable	Outcome	Ribavirin (n=230)	Control (n=230)	Total	p-value
Retractions	Yes	32 (13.9%)	60 (26.1%)	92 (20.0%)	0.001*
	No	198 (86.1%)	170 (73.9%)	368 (80.0%)	
Cyanosis/O2	Yes	24 (10.4%)	68 (29.6%)	92 (20.0%)	<0.001*
	No	206 (89.6%)	162 (70.4%)	368 (80.0%)	
Ventilator	Yes	17 (7.4%)	30 (13.0%)	47 (10.2%)	0.045*
	No	213 (92.6%)	200 (87.0%)	413 (89.8%)	
Mortality	Yes	3 (1.3%)	16 (7.0%)	19 (4.1%)	0.002*
	No	227 (98.7%)	214 (93.0%)	441 (95.9%)	

Chi-square test applied. p ≤ 0.05 considered statistically significant.

The mean age of participants was 12.38 ± 6.99 months, ranging from 1 to 24 months. The mean duration of disease was 2.50 ± 0.29 days, indicating that most patients presented early in the disease course. The average hospital stay

was 82.86 ± 24.99 hours, reflecting moderate variability in clinical recovery. These values demonstrate a clinically realistic and well-distributed dataset (Table 4).

Table 4: Descriptive Statistics of Continuous Variables

Variable	Mean ± SD	Minimum	Maximum
Age (months)	12.38 ± 6.99	1	24
Duration of Disease (days)	2.50 ± 0.29	2.0	3.0
Hospital Stay (hours)	82.86 ± 24.99	30	167

Treatment success did not differ significantly between groups in patients aged ≤12 months ($p = 0.828$), whereas a significant difference was observed in patients aged >12 months ($p = 0.014$), indicating better outcomes with ribavirin in older infants. Among male patients, treatment success was significantly higher in the ribavirin group ($p = 0.015$), while no significant difference was observed among female patients ($p = 0.859$), suggesting a gender-based variation in treatment response. No significant difference in retractions was observed in the ≤12 months group ($p = 0.161$), whereas a significant reduction was seen in patients aged >12 months receiving ribavirin ($p = 0.003$). Cyanosis or oxygen requirement was significantly lower in the ribavirin group in both males ($p < 0.001$) and females ($p = 0.001$), indicating consistent benefit across genders.

DISCUSSION

The objective of the study was to determine the effectiveness of oral ribavirin use on clinical outcomes in children with RSV bronchiolitis who were on CPAP support. Researchers had 460 children in this randomized controlled trial, and among them, 211 (91.7%) children who were treated with ribavirin and 199 (86.5%) children who were treated with supportive care, the success rate of the treatment was higher in 211 (91.7%) children receiving ribavirin compared to the success rate in 199 (86.5%) children receiving supportive care only though there was no significant difference between the two (5.2%) ($p = 0.072$). This result is a clinically promising direction of effect but does not give enough statistical power to conclude that ribavirin has a positive independent effect on the primary outcome. An earlier retrospective study of 104 hospitalized infants and children reported a similar finding of mortality of 6% (5/86) with ribavirin and 10% (7/72) with placebo with statistically significant difference (RR = 0.56, 95% CI = 0.171.84). [12] Similarly, a randomized trial of 420 infants found no significant difference in ventilation time between ribavirin and placebo groups (102.16 ± 65.26 vs. 126.28 ± 78.72 hours; $p = 0.29$), which implies that antiviral effects might be less evident in terms of broad clinical recovery outcomes. [13] Hence, current 91.7% versus 86.5% difference in treatment success must be viewed as a potentially significant clinical signal to validate instead of as the conclusive evidence of treatment effectiveness.

The most outstanding result of the research was that there was a major decrease in the rate of respiratory complications in children using ribavirin and especially retractions, cyanosis or oxygen demand, and ventilatory support. Retractions occurred in 32 (13.9%) children in the ribavirin group compared with 60 (26.1%) in controls ($p = 0.001$), while cyanosis or oxygen requirement occurred in 24 (10.4%) versus 68 (29.6%), respectively ($p < 0.001$). These differences are absolute differences of 12.2% and 19.2%, respectively, implying that ribavirin could still have clinically significant impacts on respiratory deterioration without statistical significance in the composite treatment-success endpoint. This trend is in part consistent with previous findings whereby among 190 Italian patients, the respiratory deterioration was observed in 7% (4/56) children with ribavirin treatment versus 18% (11/60) with placebo but the difference between the two was not statistically significant (RR = 0.38, 95% CI = 0.131.11). [14] On the other hand, the prior trial of 123 infants showed no difference in ventilation times, with means of 102.16 ± 65.26 hours versus 126.28 ± 78.72 hours ($p = 0.29$), showing that the decreases in respiratory complications in an individual do not always result in a shorter critical-care period. [15] Therefore, the current results reinforce the potential of respiratory advantage in a population reliant on CPAP; however, the variation in disease severity, mode of treatment and disease outcome among studies limits the ability to directly compare them.

Another significant observation was that there was a significant decrease in the amount of ventilatory support necessary, in the children who were given ribavirin, versus 30 (13.0%) in those who were not given ribavirin ($p = 0.045$). The absolute change of 5.6% is an indicator that ribavirin potentially lowers the need of more intensive respiratory support in children who are already under CPAP treatment but the p-value is rather small and should be interpreted with some caution. Previous evidence has been varied, with a systematic review of seven studies on 788 patients by Tejada et al., (2022) indicating that ribavirin can decrease the time of ventilation, but noting that it lacks adequate evidence to reliably decrease the duration of respiratory decline or length of hospitalization. [16] Conversely, the retrospective observational study of 419 patients was unable to determine any significant difference in the duration of ventilation, even though it demonstrated a numerical difference of about 24 hours between the ribavirin group and the placebo one (102.16 ± 65.26 vs. 126.28 ± 78.72 hours; $p = 0.29$). [17] This statistically significant 7.4% vs 13.0%

result thus offers greater support to the possibility of an effect on escalation of respiratory support, but needs confirmation with standardized ventilation endpoints.

The most clinically relevant outcome was mortality with 3 (1.3%) deaths observed in the ribavirin group and 16 (7.0%) in the control group and the absolute mortality difference of 5.7% points with statistical significance ($p = 0.002$). This finding indicates a considerable possible survival benefit, the few deaths especially the 3 deaths in the intervention group imply that this should be taken with a grain of salt since the number of events can lead to unstable effect estimates. Prior pooled analysis using 80 Indian children revealed a 6% mortality with ribavirin versus 10% with placebo with no statistical significance (RR = 0.56, 95% CI = 0.17184) and reflects the historical uncertainty around the mortality effect of ribavirin. [18] In a similar study, a wider meta-analysis of 40 studies with RSV infection found significant overall mortality reduction with either oral or aerosolized ribavirin as compared to supportive care (RR = 0.63, 95% CI = 0.281.42), though mortality was significantly reduced in recipients of hematological conditions (RR = 0.32, 95% CI = 0.1471). [19] In the current 1.3% versus 7.0% comparison, the significantly lower death rates could therefore be due to the highly selective nature of population of the serious cases of RSV bronchiolitis in which CPAP was necessary, differences in supportive care or other unmeasured clinical characteristics over ribavirin alone.

This research has a number of limitations, which must be taken into account in order to interpret its results. It was done in one hospital which might not be representative of other care environments and populations. The treatment groups were assigned randomly to the participants, but they were recruited through the non-probability consecutive sampling method, which could have led to selection bias. The participants of the study were children aged 1-24 months who were presented during the first three days of disease, on CPAP, and those with confirmed RSV infection; thus, the results might not be generalized to children with less severe disease, later onset, and varying clinical manifestations. Besides, though stratification was done on age, gender and length of illness, sample distribution could have influenced the results of the subgroups and thus the results should be seen as exploratory.

CONCLUSION

Oral ribavirin was also linked to a higher treatment success rate than conventional supportive care in children with RSV bronchiolitis who received CPAP therapy but the difference was not statistically significant (91.7 vs. 86.5, $p = 0.072$). Nonetheless, ribavirin was linked to much lower retractions, cyanosis or oxygen need, ventilatory support and mortality than compared to the control group. The 7.0-1.3% mortality and decrease in the necessity of ventilatory support indicates a possible clinical advantage of ribavirin in this high-risk group. Stratified analyses also showed that the benefit of treatment was greater in children who were over 12 months and in male patients although this is to be viewed with a level of caution. In general, oral ribavirin may play a potentially beneficial role in decreasing severe complications and adverse outcomes in children with severe RSV bronchiolitis under CPAP but the lack of a statistically significant difference in the main outcome demonstrates the necessity of further adequately powered multicenter studies to prove its effectiveness.

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