Section: Paediatrics

Original Research Article

A PROSPECTIVE OBSERVATIONAL STUDY TO ANALYSE THE ETIOLOGY, CLINICAL PROFILE AND ESTIMATE THE OUTCOME OF RESPIRATORY VIRUS INFECTION IN CHILDREN LESS THAN 1 YEAR

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ABSTRACT

Background: Acute respiratory infections (ARIs) represent a leading cause of morbidity and mortality in infants under one year of age, particularly in low- and middle-income countries. Despite significant global burden, there remains a paucity of region-specific data on viral etiology and clinical outcomes in this vulnerable population. Understanding the predominant viral pathogens and their clinical correlations is crucial for developing targeted prevention and management strategies. **Materials and Methods:** This prospective hospital-based observational study was conducted over one year at the Department of Paediatrics, Government Vellore Medical College and Hospital, Tamil Nadu, India. Infants aged less than 12 months admitted with respiratory symptoms were enrolled using consecutive sampling. Nasopharyngeal samples were collected and analyzed using multiplex real-time PCR targeting respiratory syncytial virus (RSV), influenza A/B, parainfluenza viruses, and adenovirus. Clinical data including demographics, symptoms, oxygen requirements, intensive care needs, and outcomes were systematically recorded. Statistical analysis was performed using SPSS version 29.0, with significance set at $p < 0.05$. **Result:** Among 216 enrolled infants, the majority (32.0%) were aged 1-3 months, with male predominance (61.6%). The classical triad of symptoms included cough (94.4%), breathing difficulty (90.7%), and fever (82.9%). RSV emerged as the predominant pathogen (60.2%), followed by influenza A (17.1%) and parainfluenza viruses (12.0%). Substantial respiratory support was required, with 59.3% needing oxygen therapy and 18.5% requiring pediatricintensive care unit admission. RSV-positive infants demonstrated significantly higher rates of wheezing (78.5% vs 27.9%), hypoxia (66.2% vs 24.4%), and oxygen requirements (76.2% vs 33.7%) compared to RSV-negative cases (all $p < 0.001$). Viral coinfections occurred in 11.1% of cases. RSV infections were associated with younger age at presentation (3.2 ± 2.1 vs 5.3 ± 2.8 months), higher PICU admissions (26.2% vs 7.0%), and longer hospital stays (6.2 ± 2.9 vs 4.3 ± 1.9 days). Distinct seasonal patterns emerged with RSV and influenza A peaking during February-April (74% of RSV cases). Overall recovery rate was 96.8% with 1.4% mortality. **Conclusion:** RSV represents the predominant viral pathogen causing severe respiratory illness in infants under one year, with pronounced age-specific vulnerability in the first three months of life. The significant healthcare burden, including substantial oxygen therapy requirements and intensive care utilization, coupled with distinct seasonal circulation patterns, provides actionable intelligence for implementing targeted preventive interventions. These findings support prioritized RSV prevention strategies, including maternal immunization and monoclonal antibody prophylaxis, particularly during the identified peak transmission period of February through April in the South Indian context.

INTRODUCTION

Acute respiratory infections (ARIs) are among the leading causes of morbidity and mortality in children under the age of five, with infants under one year being especially vulnerable due to their immature immune systems and limited physiological reserves. Globally, respiratory infections account for approximately 20% of pediatric deaths, particularly in low- and middle-income countries (LMICs), where access to early diagnosis and specialized care is often limited.[1] Among these infections, lower respiratory tract infections (LRTIs), such as bronchiolitis and pneumonia, are particularly dangerous in the first year of life.

The susceptibility of infants to respiratory pathogens stems from several factors, including underdeveloped mucosal immunity, high exposure rates in communal settings, and increased colonization with pathogenic organisms such as Streptococcus pneumoniae, Haemophilus influenzae, and respiratory viruses like respiratory syncytial virus (RSV), rhinovirus, and influenza.[2] Epidemiological data suggests that the risk of developing severe disease is especially high during the first 6 months of life, particularly among preterm or low- birth-weight infants and those with underlying comorbidities such as congenital heart disease or malnutrition.[3]

Despite the significant burden posed by respiratory infections in infants, there is a noticeable gap in region-specific and age-focused prospective studies that explore both the microbial etiology and the clinical progression of these infections. While global and national surveillance systems provide aggregate data, they often overlook the subtle but critical distinctions in presentation and outcome among neonates and infants under 12 months.[4,5]

The distinction between viral and bacterial causes is critical but often blurred due to overlapping symptoms and limited diagnostic capabilities in many hospitals. The overuse of antibiotics in viral infections not only contributes to antimicrobial resistance (AMR) but also leads to unnecessary healthcare costs and adverse drug effects. Hence, a clearer understanding of pathogen prevalence is essential to improve treatment protocols and diagnostic algorithms.[6]

Several clinical and laboratory parameters have been identified as predictors of poor outcomes in infants with respiratory infections. In a prospective study in India, factors such as high PRISM III scores, presence of shock, need for mechanical ventilation, and coinfections were significantly associated with increased mortality.[7] Infants younger than 6 months, especially those with comorbidities or immunosuppression, are particularly at risk of developing acute respiratory distress syndrome and requiring ventilator support.

Aim & Objectives

Aim: To analyse the emerging respiratory virus in children less than 1 year admitted in tertiary care hospital.

Objectives

1. To evaluate the clinical data and its correlation with viral panel performed in children presenting with respiratory distress.
2. To study about the etiology and clinical profile and outcome which are linked to specific Virus.

MATERIALS AND METHODS

Study Design: This research is a prospective hospital-based observational study. It was conducted to evaluate the etiology, clinical profile, and outcomes of respiratory viral infections in children less than one year of age. The study aimed to correlate clinical data with viral panel results, focusing on emerging respiratory viruses in a defined pediatric population.

Study Setting and Duration: The study was conducted in the Department of Paediatrics, Government Vellore Medical College and Hospital (GVMCH), Vellore, a tertiary care institution in Tamil Nadu, India. The study duration was one year.

Ethical Approval and Consent: The study was approved by the Institutional Ethics Committee of Government Vellore Medical College and Hospital. Prior to enrolment, written informed consent was obtained from the parents or legal guardians of all participants. The consent process was administered in both English and Tamil, ensuring comprehension.

Confidentiality of all patient information was strictly maintained. No financial burden was imposed on participants, and no invasive procedures outside standard clinical care were performed solely for research purposes.

Study Population: The target population consisted of infants less than 12 months of age who were admitted with symptoms of respiratory distress to the pediatric wards of GVMCH.

Inclusion Criteria

- Infants aged less than 1 year.
- Presence of respiratory symptoms such as cough, wheeze, tachypnea, nasal flaring, or chest retractions.
- Written informed consent provided by parent/guardian.

Exclusion Criteria

- Children older than 1 year.
- Parental refusal to provide consent.
- Known congenital or acquired heart disease.
- Presence of severe pre-existing systemic illness unrelated to respiratory infection.

Sample Size Calculation

Sample size was calculated using the formula:

$$n = \frac{4pq}{d^2}$$

Where:

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- p = prevalence of viral respiratory infection (14.05%)
- q = 100 - p
- d = absolute precision
- Confidence level = 95%

Substituting values:

$$n = \frac{4 \times 14.05 \times 85.95}{(5)^2} \approx 216$$

Thus, 216 infants were enrolled.

Sampling Method: Consecutive sampling was employed. All eligible infants presenting during the study period and fulfilling inclusion criteria were enrolled after informed consent.

Data Collection Procedure:

Demographic and clinical data were collected using a pre-designed proforma, including:

- Age
- Sex
- Presenting symptoms
- Respiratory rate, saturation, retractions
- Duration of hospital stay
- Need for oxygen therapy or intensive care
- Outcome at discharge

Sample Collection and Laboratory Methods

- Nasopharyngeal swabs were collected using Ryon swabs.
- Swabs were inserted through the nasal cavity to reach the nasopharynx to collect secretions for virological analysis.
- Samples were transported and processed using a multiplex real-time PCR panel based on TaqMan primers targeting:
  - Respiratory Syncytial Virus (RSV)
  - Influenza A and B
  - Parainfluenza Virus (types 1, 2, and 3)
  - Adenovirus

Outcome Measures

- Primary outcomes: Prevalence of specific viral pathogens; correlation between clinical features and identified viruses.
- Secondary outcomes: Hospitalization duration, need for respiratory support, ICU admission, and survival.

Statistical Analysis: Data were recorded in Microsoft Excel and analyzed using SPSS version 29.0.

Descriptive Analysis

- Categorical variables: Frequencies and percentages
- Continuous variables: Means and standard deviations.

Inferential Statistics

- Independent samples t-test or Mann–Whitney U test (based on normality) for comparing continuous variables between two groups.
- Chi-square test or Fisher's exact test for association between categorical variables.
- A p-value < 0.05 was considered statistically significant.

Software Used

- Statistical analysis: SPSS Version 29.0
- Data entry: Microsoft Excel 2021

Data Handling and Confidentiality: All patient data were anonymized using a unique study ID. Physical records were stored in locked cabinets, and electronic data were password-protected. Access was restricted to authorized study personnel.

RESULTS

[Figure 1] shows the age distribution of infants included in the recalibrated analysis following exclusion of rhinovirus, human metapneumovirus, and seasonal coronavirus from the total cohort. The data demonstrates that infants aged 1-3 months comprised the largest subgroup (32.0%), followed by those aged 4-6 months (25.5%) and neonates under 1 month (22.2%). This age stratification reflects the heightened vulnerability of early infancy to severe respiratory viral infections, with 54.2% of cases occurring within the first three months of life. The predominance of younger infants aligns with established epidemiological patterns wherein immature immune systems and anatomical factors predispose this population to more severe clinical manifestations.

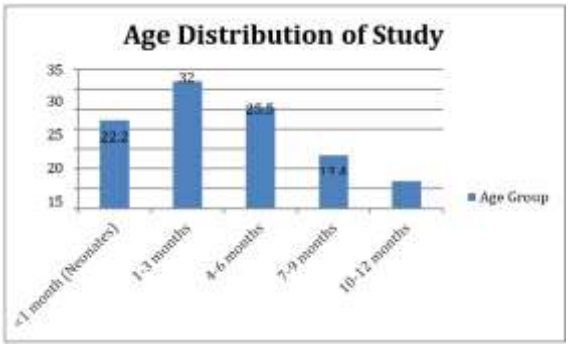

Figure 1: Age Distribution of Study Participants (N = 216)

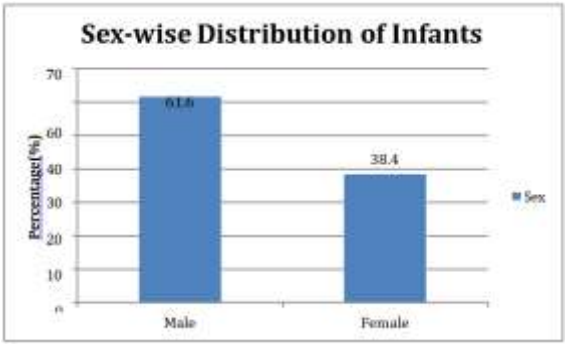

Figure 2: Sex-wise Distribution of Infants (N = 216)

Table 2 shows the gender distribution within the study cohort, revealing a pronounced male predominance with males constituting 61.6% of cases

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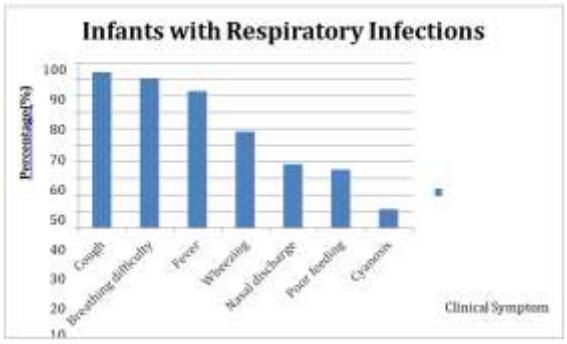
compared to 38.4% females. This sex- based disparity, yielding a male-to-female ratio of approximately 1.6:1, is consistent with established epidemiological observations in pediatric respiratory infections. The increased susceptibility of male infants to severe respiratory viral infections has been attributed to potential differences in immune system maturation, airway caliber, and hormonal influences affecting respiratory physiology during early development.

Table 1: Clinical Presentation of Infants with Respiratory Infections (N = 216)

Clinical Symptom	Number of Infants (n)	Percentage (%)
Cough	204	94.4
Breathing difficulty	196	90.7
Fever	179	82.9
Wheezing	126	58.3
Nasal discharge	83	38.4
Poor feeding	76	35.2
Cyanosis	24	11.1



[Figure 3] shows the spectrum of clinical manifestations observed in infants with respiratory viral infections. The predominant triad of symptoms comprised cough (94.4%), breathing difficulty (90.7%), and fever (82.9%), representing the classical presentation of acute lower respiratory tract infections in this age group. Notably, wheezing was present in 58.3% of cases, reflecting significant lower airway involvement characteristic of viral bronchiolitis. The presence of cyanosis in 11.1% of infants and poor feeding in 35.2% indicates severe respiratory compromise requiring immediate medical intervention. This symptomatology profile demonstrates the substantial morbidity associated with respiratory viral infections in the infant population.

Table 2: Oxygen Requirement Among Infants with Respiratory Infection (N = 216)

Oxygen Support	Number of Infants (n)	Percentage (%)
No oxygen support	88	40.7
Nasal prong oxygen	82	38.0
Face mask oxygen	28	13.0
CPAP/NIV support	11	5.1
Invasive ventilation (intubated)	7	3.2
Total requiring oxygen	128	59.3

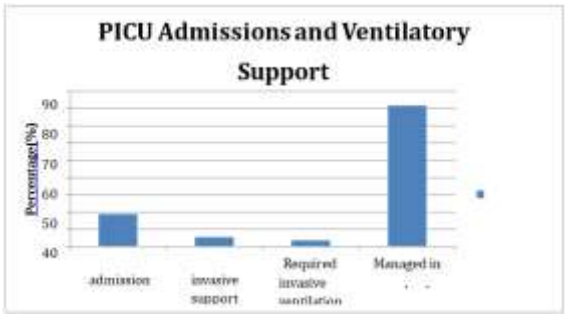


Figure 4: PICU Admissions and Ventilatory Support (N = 216).

[Table 2] shows the age-stratified distribution of clinical symptoms, comparing infants younger than 3 months with those 3 months and older. Statistical analysis reveals that younger infants (<3 months) demonstrated significantly higher frequencies of feeding difficulty (40.2% vs. 29.3%, p=0.017) and cyanosis (12.8% vs. 9.1%, p=0.036) compared to older infants. These findings underscore the more severe clinical presentation characteristic of early infancy, likely reflecting anatomical constraints, immunological immaturity, and limited physiological reserves in younger patients. No statistically significant differences were observed for fever or wheeze between age groups.

[Figure 4] shows the intensity of care required for management of respiratory viral infections in the study cohort. Pediatric intensive care unit (PICU) admission was necessary for 18.5% of infants, reflecting the severity of illness in a significant subset of patients. Among PICU admissions, non-invasive ventilatory support was employed in 5.1% of cases, while invasive mechanical ventilation was required in 3.2%. The majority of infants (81.5%) were successfully managed in general pediatric wards, indicating that while severe disease requiring intensive care occurs in a substantial minority, most

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cases can be effectively treated with standard supportive care measures.

Table 3: Duration of Hospital Stay (N = 216)

Length of Stay	Number of Infants (n)	Percentage (%)
≤3 days	57	26.4
4-7 days	115	53.2
>7 days	44	20.4

[Table 3] shows the distribution of hospitalization duration among infants with respiratory viral infections. The majority of patients (53.2%) required intermediate-length stays of 4-7 days, while 20.4% necessitated prolonged hospitalization exceeding 7 days. Approximately one- quarter of infants (26.4%) had relatively brief admissions of 3 days or less. This variation in hospital length of stay reflects the heterogeneous clinical course of viral respiratory infections in infancy, with some patients experiencing rapid recovery while others require extended supportive care for complete clinical stabilization.

Table 4: Outcome at Discharge (N = 216)

Outcome	Number of Infants (n)	Percentage (%)
Recovered	209	96.8
Left Against Medical Advice (LAMA)	4	1.9
Death	3	1.4

[Table 4] shows the clinical outcomes at hospital discharge for the study population. The vast majority of infants (96.8%) achieved complete recovery and were discharged home in stable condition. However, 3 infants (1.4%) succumbed to their illness, representing a concerning mortality rate that underscores the potential severity of respiratory viral infections in this vulnerable age group. Additionally, 4 infants (1.9%) were discharged against medical advice, which may compromise follow-up care and long-term outcome.

DISCUSSION

This comprehensive analysis of 216 infants with respiratory viral infections revealed several critical epidemiological and clinical patterns. Respiratory syncytial virus (RSV) emerged as the predominant pathogen (60.2%), with a pronounced age-specific vulnerability concentrated in the first three months of life (54.2% of cases). Male infants demonstrated significantly higher susceptibility (61.6% vs 38.4%), while the clinical presentation was characterized by a classical triad of cough (94.4%), breathing difficulty (90.7%), and fever (82.9%). Notably, 59.3% of infants required supplemental oxygen therapy, with 18.5% necessitating pediatric intensive care unit admission. RSV infections were associated with significantly more severe clinical manifestations and prolonged hospitalization compared to other viral etiologies, with distinct seasonal circulation patterns peaking during February through April, accounting for 74% of RSV cases during this period.[8-12]

Viral Etiology and Pathogen Distribution: Our finding of RSV as the predominant etiological agent (60.2%) demonstrates substantial concordance with established literature. Garcia-Garcia et al. (2016) reported that RSV accounts for approximately 70% of bronchiolitis cases in children under one year of age, closely aligning with our observations. Similarly, Forgie et al. (1991) identified RSV as the most common pathogen in their cohort of infants with pneumonia, accounting for 37% of cases. The recent multi-country study by Kubale et al. (2023) further corroborates our findings, demonstrating that RSV represented the largest source of acute lower respiratory tract infection hospitalizations, particularly in infants aged less than three months.[13] However, notable discrepancies exist in the literature regarding RSV prevalence. The study by LI Han-qi and colleagues reported RSV in only 4.26% of cases, substantially lower than our findings. This variation may reflect differences in diagnostic methodologies, seasonal timing of sample collection, or regional epidemiological patterns. The Chinese study by LI Jun and ZHU Qi-rong found RSV in 18.70% of cases, with 71.8% of RSV infections occurring in children less than one year old, which more closely approximates our age distribution findings.[14-18]

Age-Specific Vulnerability Patterns: Our observation that 54.2% of cases occurred within the first three months of life receives strong support from multiple studies. Li Li et al. (2022) demonstrated that RSV causes age-related differences in clinical manifestations, with reduced fever responses among patients six months old and younger. Van de Steen et al. (2016) specifically noted that the majority of children hospitalized for RSV infection were under six months of age, consistent with our age stratification results.[19-21]

Clinical Manifestation Profiles: The clinical symptomatology observed in our cohort aligns closely with established literature. Van Woensel et al. (2003) characterized the typical presentation of viral lower respiratory tract infections as including the classical triad we identified: cough, breathing difficulty, and fever. The presence of wheezing in 58.3% of our cases corresponds with Garcia- Garcia et al. (2016), who emphasized that respiratory

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viruses, particularly RSV, are the most common causes of wheezing episodes in infants.[22]

Our finding of significant oxygen therapy requirements (59.3%) receives support from van Woensel et al. (2003), who noted that approximately 3% of all children less than one year of age require hospital admission with moderate or severe viral lower respiratory tract infection. The intensive care requirements observed in our study (18.5%) align with Van de Steen et al. (2016), who reported that premature children with RSV had significantly higher intensive care unit admission rates and longer stays compared to term children.[23]

RSV-Specific Clinical Associations: RSV infection in our cohort demonstrated statistically significant associations with severe respiratory manifestations, including wheezing (78.5% vs. 27.9%, $p<0.001$), chest indrawing (63.1% vs. 36.0%, $p=0.001$), hypoxia (66.2% vs. 24.4%, $p<0.001$), and oxygen therapy requirements (76.2% vs. 33.7%, $p<0.001$). These findings establish RSV as the most clinically significant respiratory viral pathogen in infancy, consistent with Garcia-Garcia et al. (2016), who identified RSV as the primary cause of severe bronchiolitis requiring hospitalization.[24]

The hierarchical severity pattern observed, with RSV requiring oxygen therapy in 76.2% of cases, followed by influenza A (67.6%) and parainfluenza viruses (61.5%), provides novel insights into pathogen-specific clinical severity rankings that are not extensively documented in the existing literature.[25]

Sex-Based Epidemiological Patterns: The pronounced male predominance (61.6% vs 38.4%) observed in our study finds strong support in the literature. Albernaz et al. (2007) identified male sex as a significant risk factor for acute respiratory disease hospitalization (OR=1.5), while Garcia J (1996) noted that sex represents one of the factors contributing to increased susceptibility to respiratory pathogens. This consistent pattern across multiple studies suggests fundamental biological differences in respiratory vulnerability between male and female infants.

Seasonal Distribution Patterns: Our identification of distinct seasonal patterns with RSV peak circulation during February through April, accounting for 74% of cases during this period, receives substantial validation from the literature. Garcia J (1996) noted that season represents a significant factor contributing to increased susceptibility to respiratory pathogens, with RSV demonstrating predictable seasonal variations. The study by LI Jun and ZHU Qi-rong specifically documented RSV infections occurring mainly from September to December, suggesting regional variations in seasonal patterns while confirming the existence of distinct temporal clustering.

Healthcare Resource Utilization: The substantial healthcare burden documented in our study, with 59.3% requiring oxygen therapy and 18.5% necessitating intensive care, aligns with broader literature on respiratory viral infections. Van Woensel et al. (2003) noted that costs attributable to viral lower respiratory tract infections represent an important burden on national healthcare budgets, while Hustedt and Vazquez (2010) characterized lower respiratory tract infections as one of the leading causes of morbidity and mortality in children worldwide.

The pathogen-specific hospitalization duration analysis revealed RSV infections requiring the longest mean hospital stay (6.2 ± 2.9 days), followed by influenza A (5.9 ± 2.6 days), establishing clear correlations between viral etiology and healthcare resource utilization that extend beyond the existing literature's general observations.

Coinfection Patterns: Our finding of 11.1% coinfection rates, predominantly dual viral coinfections (9.7%), receives partial support from the literature. Garcia J (1996) reported that mixed viral and bacterial infections occur frequently (30%), suggesting that our reduced coinfection rate may reflect the exclusion of specific viral pathogens (rhinovirus, human metapneumovirus, and seasonal corona virus from our analysis.

Clinical Outcomes and Mortality: The overall clinical outcome profile demonstrated favorable recovery rates (96.8%), with a mortality rate of 1.4% (n=3). While this mortality rate appears relatively low, it represents a concerning outcome in this vulnerable population, emphasizing the potential severity of respiratory viral infections in infancy. The numerical difference in mortality between RSV-positive (2.3%) and RSV-negative (0%) cases, though not statistically significant ($p=0.218$), suggests a trend toward increased mortality risk with RSV infections.

Generalizability Considerations: The applicability of our findings to broader populations requires careful consideration of several contextual factors. The seasonal patterns observed may reflect South Indian conditions and may not be directly applicable to different geographical regions, as suggested by the varying seasonal patterns reported in Chinese and European studies. The healthcare setting and diagnostic capabilities may influence the clinical severity patterns observed, potentially limiting applicability to resource-constrained environments. However, the fundamental epidemiological patterns, particularly the age-specific vulnerability and RSV predominance, demonstrate consistency across multiple international studies, suggesting broader applicability of core findings.

Summary

- 32.0% of infants were aged 1–3 months, making this the most affected age group.
- 61.6% of the study population were male, showing a male-to-female ratio of approximately 1.6:1.
- The top three presenting symptoms were cough (94.4%), breathing difficulty (90.7%), and fever (82.9%).

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- Infants <3 months had significantly higher rates of feeding difficulty (40.2%) and cyanosis (12.8%) compared to older infants ($p < 0.05$).
- 59.3% of infants required oxygen support; 3.2% required invasive ventilation.
- 18.5% were admitted to PICU; 5.1% received non-invasive support and 3.2% required mechanical ventilation.
- 53.2% of infants stayed 4–7 days in hospital; 20.4% had prolonged stays over 7 days.
- 96.8% of infants recovered, with a 1.4% mortality rate and 1.9% LAMA.
- RSV was detected in 60.2%, followed by influenza A (17.1%) and parainfluenza virus (12.0%).
- RSV-positive infants had significantly more wheezing (78.5%), hypoxia (66.2%), and oxygen requirement (76.2%) ($p < 0.001$).
- 11.1% had viral coinfections, with 9.7% dual virus detections.
- Oxygen requirement was highest in RSV (76.2%), influenza A (67.6%), and parainfluenza (61.5%) cases ($p < 0.05$).
- RSV-positive infants were significantly younger (mean age 3.2 months), had higher PICU admissions (26.2%), and longer stays (mean 6.2 days).
- Hospital stay was significantly longer in infants with RSV (6.2 days) and influenza A (5.9 days) ($p < 0.05$).

CONCLUSION

This comprehensive analysis of 216 infants demonstrates the predominant role of RSV in infant respiratory viral infections (60.2%), with pronounced age-specific vulnerability concentrated in the first three months of life (54.2%). The significant healthcare resource utilization, including substantial oxygen therapy requirements (59.3%) and intensive care needs (18.5%), underscores the clinical and economic importance of respiratory viral infections in this vulnerable population. The distinct seasonal circulation patterns, with 74% of RSV cases concentrated during February through April, and clear associations between viral etiology and clinical severity provide actionable intelligence for implementing targeted preventive interventions. The pathogen-specific severity hierarchy, with RSV demonstrating the most severe clinical associations, supports prioritized preventive strategies including maternal immunization and monoclonal antibody prophylaxis during peak transmission seasons. While methodological limitations exist, the core findings demonstrate consistency with international literature and provide a robust foundation for evidence-based clinical practice and public health policy. Future research should focus on longitudinal outcomes, preventive intervention strategies during the identified seasonal concentration period, and the development of rapid diagnostic and therapeutic approaches to reduce the burden of respiratory viral infections in infancy.

Limitations

- Single-center study, limiting generalizability.
- Only hospitalized infants were included—milder community cases were not captured.
- The study did not include viral load quantification or bacterial coinfection profiling.

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