

Respiratory Syncytial Virus Infection among Adults after Hematopoietic Stem Cell Transplantation

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Abstract

Introduction: Respiratory syncytial virus (RSV) is a common cause of morbidity among hematopoietic stem cell transplant (HSCT) recipients, with RSV-associated lower respiratory tract infection carrying high mortality rates. There have been no large studies till date, describing the incidence, clinical features, and outcomes of RSV infection among adult HSCT recipients in India. **Methods:** A prospective cohort of 100 adults who underwent HSCT was followed up for a maximum period of 18 months starting from the date of transplantation for any episode of respiratory tract infectious disease (RTID). Respiratory samples were collected for laboratory confirmation of the presence and subtyping of RSV by real-time reverse transcriptase-polymerase chain reaction. **Results:** The study population comprised of 66% (66/100) males and 34% (34/100) females. Autologous HSCT recipients constituted 78% (78/100) and allogeneic HSCT recipients constituted 22% (22/100) of the study population. The incidence of RSV-RTID among adults after HSCT was 0.82/100 patient months. Most cases occurred during the winter season and the predominant subtype was RSV-A (9/11, 81.8%). Lower RTID was the most common clinical diagnosis made at presentation (9/11, 81.8%). Female gender was predictive of RSV-RTID (log rank $P = 0.002$). All the RSV-RTID episodes recovered completely without targeted therapy. **Conclusion:** RSV is a significant cause of morbidity among adult HSCT recipients in India. Prophylaxis and treatment measures need to be instituted after a proper risk-benefit assessment. Longitudinal studies with larger sample sizes are needed to confirm these results.

Keywords: Hematopoietic stem cell transplantation, HSCT, India, respiratory syncytial virus

INTRODUCTION

There are more than 80,000 hematopoietic stem cell transplantations done each year worldwide and over a thousand are performed each year in India.^[1,2] Hematopoietic stem cell transplant (HSCT) recipients carry a high risk for severe disease due to respiratory syncytial virus (RSV) infection. RSV infection progresses from upper respiratory tract infection to lower respiratory tract infection in 30%–40% of HSCT recipients with consequent mortality close to 50% which is significantly higher than that caused by other respiratory viruses.^[3,4] Indian data on morbidity and mortality due to RSV infection and disease among adult HSCT recipients are very limited. This study describes the incidence, clinical features, seasonality, subtype dominance, and outcomes of RSV infection among adults who received HSCT at a tertiary care center in Delhi, India.

METHODS

This study was a prospective cohort study conducted at a tertiary care and transplant center between January 2017 and

August 2021. It was approved by the institute ethics committee and all participants gave informed consent prior to their inclusion in the study.

Based on convenient sampling, 100 patients who were 18 years or older and underwent hematopoietic stem cell transplantation at the institute were consecutively recruited during the study. People whose age at the time of HSCT was <18 years and who received palivizumab were excluded from the study.

Clinical data including details about the underlying hematological/oncological disorder, type of graft and comorbidities were collected at the time of recruitment.

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Subjects were followed up for new onset of any respiratory illness, starting from the day of HSCT to 18 months after transplant or death whichever was earlier. After discharge from hospital, patients were followed up by telephone every month and advised to visit the study center if any respiratory symptom appeared. Presenting symptoms, clinical signs, chest imaging reports, and relevant blood investigations were recorded on a self-designed pro forma for symptomatic patients at the time of presentation. Only symptomatic patients were subjected to laboratory testing to avoid detecting episodes of infection without disease.

Definitions used

The adapted-European center for disease prevention and control definition (based on the fourth European conference on infections in leukemia) for respiratory tract infectious disease (RTID) was used. The possible cases, that is, those fitting into clinical criteria (new onset of symptoms and at least one of the four respiratory symptoms: cough, sore throat, coryza, or shortness of breath along with clinician's judgment that the illness is due to an infection) were subject to laboratory testing with real-time reverse transcriptase polymerase chain reaction (RT-PCR) for RSV.

Upper RTID (URTID) was defined as RSV detected in an upper respiratory tract specimen together with the presence of any of the symptoms such as sore throat, coryza or nasal congestion, and not fulfilling the criteria for lower RTID (LRTID) (see below).

LRTID was defined as detection of RSV in respiratory samples preferably from lower respiratory tract along with presence of any of the following: cough with sputum production, breathlessness, chest pain or discomfort, hypoxia or pulmonary infiltrates.

Sample collection and processing

Two samples-one each of nasal and throat swabs were collected from the acutely symptomatic patient using nylon swabs and transferred into 3 ml of reconstituted HiViral™ (HiMedia, India) viral transport medium. They were processed for RSV by real-time RT-PCR in a biosafety level-2 laboratory.

A descriptive analysis was performed on the obtained data. Categorical variables were expressed as numbers/frequency (percentages). The continuous variables were expressed as mean and standard deviation (SD) (for normally distributed data) or median with minimum and maximum values (in case of skewed data). Age was arbitrarily categorized into < and ≥50 years. Platelet count was categorized into two groups < and ≥150,000/μl based on the definition for thrombocytopenia as below the 2.5th lower percentile of normal platelet count distribution. The absolute neutrophil count and absolute lymphocyte count were categorized into < and ≥500 cells/μl, and < and ≥200 cells//μl, respectively based on the severe neutropenia and lymphopenia being listed as risk factors for severe RSV disease in previous publications.^[3]

Statistical analysis

All statistical analyses were done in StataCorp. 2019. Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC. The various factors associated with RSV infection were analyzed using Chi-square test (for larger numbers) or Fisher's exact test (for numbers <5) for categorical variables, Mann-Whitney test for continuous variables with skewed distribution and *t*-test for continuous variables with normal distribution.

RESULTS

A total of 100 adult HSCT recipients were recruited between January 2017 and February 2020 and followed up for 18 months from the day of transplant for any episode of acute respiratory illness.

The patients had a mean age ± SD of 41.8 ± 14.8 years. Males constituted 66% (66/100) and females 34% (34/100) of the study population.

The median (minimum, maximum) follow-up period was 548 (8, 548) days. At the end of the study, 72 (72%) were alive and 28 (28%) had expired. Among these, 16 deaths occurred outside the study center and their terminal event could not be traced. Among the 12 deaths that occurred at the institute, none were related to RSV infection.

The total number of possible cases of RTID recorded in the study population was 318, i.e., a mean of 3 episodes per patient. Out of these, 158 episodes were subject to laboratory confirmation for the presence of RSV ribonucleic acid (RNA) in the respiratory samples. 135 among these were LRTID episodes and 23 were URTID episodes.

A total of 11 episodes tested positive for RSV by real-time RT-PCR. The incidence density of RSV-RTID among adults after hematopoietic stem cell transplantation calculated from our study is 0.82/100 patient months. The subtypes of RSV detected are described in Table 1.

Among the patients with RSV-RTID, eight were females and 3 were male with a mean age ± SD of 46.4 ± 16.1 years. Female gender was predictive of RSV-RTID (time to event analysis, log rank *P* = 0.002) [Figure 1].

The association of RSV-RTID with age, gender, underlying hematological/oncological disorder, type of stem cell graft,

Table 1: Respiratory syncytial virus subtypes and the clinical diagnosis at presentation among respiratory syncytial virus - respiratory tract infectious disease episodes (n=11)

Type of infection	Frequency (%)	
	URTID	LRTID
RSV subtype A	2 (22.2)	7 (77.8)
RSV subtype B	0 (0)	2 (100)

RSV: Respiratory syncytial virus, URTID: Upper respiratory tract infectious disease, LRTID: Lower respiratory tract infectious disease

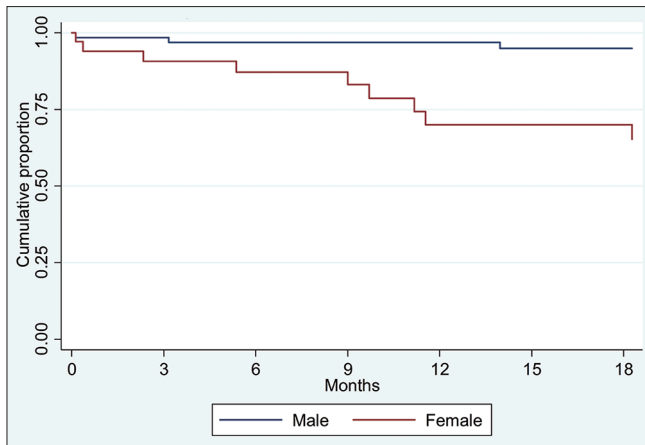


Figure 1: Kaplan–Meier plot showing RSV RTID-free survival estimates among men (blue) and women (red). Log rank $P = 0.002$, RSV: Respiratory syncytial virus, RTID: Respiratory tract infectious disease

time to onset of illness after HSCT, and various hematological parameters at presentation, are described in Table 2.

Six patients who developed RSV-RTID had preexisting comorbidities in addition to the hematological/oncological disorder. Diabetes mellitus was present in 1/11 (9.1%), hypertension in 3/11 (27.3%), hypothyroidism in 3/11 (27.3%), bronchial asthma in 1/11 (9.1%) and chronic kidney disease in 1/11 (9.1%). The RTID cases showed clustering in winter season. 9/11 (81.8%) of cases occurred in the months from October to February which coincides with winter in Delhi [Figure 2].

The presenting symptoms of RSV-RTID included nasal discharge (11/11, 100%), cough (10/11, 90.9%), sputum production (9/11, 81.8%), headache (6/11, 54.5%), sore throat (5/11, 45.5%), fever (3/11, 27.3%), chills (3/11, 27.3%), excessive fatigue (2/11, 18.2%), breathlessness (2/11, 18.2%), hemoptysis (1/11, 9.1%), vomiting (1/11, 9.1%), and diarrhea (1/11, 9.1%).

The findings on clinical examination were nonspecific. None of the presenting symptoms or signs was found to be associated with RSV detection in a statistically significant manner.

Radiological investigations including chest X-ray or computed tomography of chest revealed multifocal infiltrates in chest in 3/11 (27.3%) of RSV-RTID patients.

All the RSV-RTID episodes recovered without any targeted treatment with ribavirin or intravenous immunoglobulin, with no mortality during the RSV-RTID episodes.

Four among the 11 patients who underwent pulmonary function test after 1-year of RSV-RTID showed mild-to-moderate decrease in diffusing capacity of lungs for carbon monoxide (DLCO). No obstructive or restrictive patterns were seen on spirometry.

DISCUSSION

RSV is an enveloped virus with a nonsegmented, single stranded, negative sense RNA genome, of the genus *Pneumovirus* under

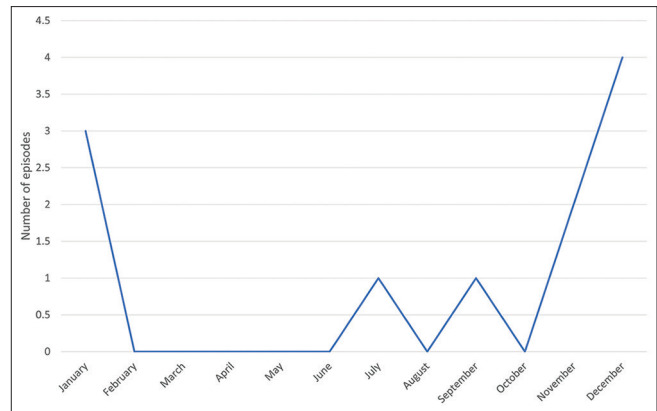


Figure 2: Seasonality of RSV respiratory tract infectious disease episodes, RSV: Respiratory syncytial virus

the family *Paramyxoviridae*. There are two heterotypic strains of RSV that are antigenically distinct, classified as subtypes A and B based on the antigenic properties of the structural components of the virus.^[5] Laboratory testing of respiratory secretions is required for confirmation of RSV infection because its clinical features and seasonality overlap considerably with those of other community-acquired respiratory viruses.

We found that the incidence of RSV-RTID in post-HSCT adult patients is 0.82/100 patient months, or in other words, an attack rate of 11%. This is higher than that seen among adults in the general population.^[6,7] Rates varying from 4% to 12% have been reported previously among HSCT recipients.^[8-13]

Although engraftment occurs early after HSCT, full immune reconstitution occurs gradually over 12–18 months during which period the risk of infection remains high. The timeline of RSV infection observed in various studies ranges from immediately after transplant up to 2 years later.^[14] A study by Srinivasan *et al.* found increased number of infections with RSV (15/622, 2%) in the period between 101 days and 2 years after allogeneic stem cell transplantation compared to 0–30 days (7/759, 1%) or 31–100 days (10/735, 1.3%) after transplantation.^[15] In our study, we found that overall, 6/11 (54.5%) RSV-RTID occurred in the period from 101 days post-HSCT till end of follow-up, 3/11 (27.3%) occurred in the 0–30 days' interval after HSCT and 2/11 (18.2%) occurred in the 31–100 days' interval.

RSV outbreaks in the community or healthcare setting may have either subtype A or subtype B dominating over the other. Subtype dominance can vary between and within yearly outbreaks.^[16-23] Few studies have suggested that RSV A is more virulent leading to a more severe disease.^[24-26] This pathogenic outcome may be in part due to the capacity of group A viruses to replicate better than the group B viruses and higher antigenicity.^[27] In our study, 9/11 (81.8%) infections were caused by RSV-A whereas 2/11 (18.2%) were caused by RSV-B [Table 1].

Many studies have found that RSV infection becomes clinically significant more frequently in allogeneic stem cell transplant recipients compared to autologous stem cell recipients due to

Table 2: Association of different variables with respiratory syncytial virus-associated respiratory tract infectious disease

Variable	RSV detected, frequency (%)		P
	Yes	No	
Age (years)			
<50	6 (54.5)	60 (67.4)	0.479
≥50	5 (45.5)	29 (32.6)	
Gender			
Male	3 (27.3)	63 (70.8)	0.004
Female	8 (72.7)	26 (29.2)	
Type of graft			
Autologous	10 (90.9)	68 (76.4)	0.273
Allogenic	1 (9.1)	21 (23.6)	
Underlying disorder			
Lymphoma	3 (27.3)	25 (28.1)	0.311
Leukemia	1 (9.1)	20 (22.5)	
Plasma cell disorder	6 (54.5)	36 (40.4)	
Solid tumor	0	2 (2.2)	
Myelofibrosis	0	1 (1.1)	
Aplastic anemia	0	5 (5.6)	
Amyloidosis	1 (9.1)	0	
Clinical diagnosis at presentation			
URTID	2 (18.2)	27 (30.3)	0.402
LRTID	9 (81.8)	62 (69.7)	
Absolute neutrophil count (/μl)			
<500	2 (18.2)	32 (36)	0.327
≥500	9 (81.8)	57 (64)	
Absolute lymphocyte count (/μl)			
<200	2 (18.2)	31 (34.8)	0.562
≥200	9 (81.8)	58 (65.2)	
Platelet count (/μl)			
<150,000	10 (90.9)	62 (69.7)	0.139
≥150,000	1 (9.1)	27 (30.3)	
Continuous variables			
Hemoglobin (mean±SD)	9.41±1.3	10.2±1.9	0.177
Hematocrit (mean±SD)	29.7±4.6	31.7±5.4	0.254
Median total white blood cell count (minimum-maximum)	5730 (10-10,040)	3290 (20-131,800)	0.285
Median time interval in days between HSCT and onset of RTID (minimum-maximum)	161 (4-419)	79 (0-522)	0.366

URTID: Upper respiratory tract infectious disease, LRTID: Lower respiratory tract infectious disease, HSCT: Hematopoietic stem cell transplantation, RSV: Respiratory syncytial virus, RTID: Respiratory tract infectious disease, SD: Standard deviation

an interplay of various factors such as transplantation modality, use of total body irradiation, presence of graft versus host disease (GVHD), and GVHD prophylaxis.^[15,28] In our study, 78% of subjects had autologous stem cell transplant and only 22% had allogeneic transplant, and only one allogeneic transplant recipient had a laboratory-confirmed RSV-RTID.

This is probably one of the reasons for good outcomes of RSV-RTID seen in this study.

Co-pathogens identified together with RSV during the RTID episodes included parainfluenza virus (PIV)-1, PIV-3, and PIV-4 in three RSV-infected patients with LRTID. One patient developed pneumonia and acute respiratory distress syndrome due to influenza A (H3N2) 3 months after he recovered from RSV-LRTID, and succumbed at a local hospital.

A gender predisposition to RSV respiratory tract infection or disease has not been reported previously. However, in our study, we found that females were more prone to have RSV infection, which has to be confirmed and explored further in larger studies. None of the female patients was pregnant during the RSV-RTID episodes.

The immunodeficiency scoring index developed from the MD Anderson Cancer center has been validated to predict progression to LRTID and helps to decide regarding use of ribavirin in the URTID stage.^[29] However, the prognostic value of this scoring system for mortality has not been consistent across studies.^[30] This tool was not very useful in our study population as majority of them (9/11, 81.8%) already had LRTID at presentation.

Pulmonary sequelae of HSCT such as bronchiolitis obliterans, bronchiolitis obliterans with organizing pneumonia, and idiopathic pneumonia syndrome are seen predominantly after allogeneic HSCT and have been linked to various factors including previous infections, pretransplant conditioning regimen and type of graft.^[31] For the patients with RSV-RTID in whom decreased DLCO was seen a year after the episode in our study, invasive procedures such as bronchoscopy or lung biopsy were not performed as the patients remained clinically stable and asymptomatic. Sequelae like asthma has been linked to RSV infection in infancy, but their prevalence falls with age and such a sequel is not seen with infection in adulthood.^[32]

Our study had some limitations. It was a single-center study. As only 22% of the study subjects were residents of the state where the study center is located, many possible RTID episodes recorded during follow-up could not be subject to laboratory testing. Larger studies involving multiple transplant centers in India may resolve these limitations in future studies.

CONCLUSION

RSV is a significant cause of morbidity among adult hematopoietic stem cell transplant recipients in India. Prophylaxis and treatment measures need to be instituted after a proper risk-benefit assessment. Longitudinal studies with larger sample sizes are needed to confirm these results.

Research quality and ethics statement

This study was approved by the Institutional Ethics Committee (Institute Ethics Committee for Post Graduate Research, All India Institute of Medical Sciences, Ansari Nagar, New Delhi IEC/PG-713/January 19, 2017/, OT-3/2017, OT-6/June

28, 2018). The authors followed the EQUATOR Network guidelines for cohort studies during the conduct of this research project.

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Conflicts of interest

There are no conflicts of interest.

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