Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Hospitalizations and LOS were lower for pts on MBV than IAT. Pts who received MBV rescue reported lower hospitalization rates on or after rescue than pre-rescue. Reducing hospitalizations is critical for alleviating disease burden to healthcare systems.

Hospital admission rates and LOS per patient by treatment

	On-treatment phase[a]		Full study period[b]	
	MBV n=235	IAT n=117	MBV n=235	IAT n=117
Hospitalizations				
Patients with ≥1 admission, n (%)	75 (31.9)	43 (36.8)	125 (53.2)	65 (55.6)
Adjusted incidence rate, admissions/person/year (95% CI)	2.74 (2.22, 3.38)	4.20 (3.12, 5.67)	2.49 (2.12, 2.93)	3.20 (2.48, 4.12)
Adjusted difference in rates of hospital admissions, IRR (95% CI)	0.65 (0.45, 0.94)		0.78 (0.58, 1.05)	
Percent reduction for MBV compared with IAT	34.8% p=0.021		22.1% p=0.102	
LOS				
LOS per patient, mean no. of days (SD)	3.1 (7.1)	3.5 (7.6)	9.6 (16.1)	9.7 (22.7)
Adjusted duration of LOS, days/person/year (95% CI)	13.27 (8.89, 19.82)	28.73 (16.34, 50.52)	34.29 (25.89, 45.42)	48.88 (32.77, 72.92)
Adjusted difference in LOS, IRR (95% CI)	0.46 (0.23, 0.92)		0.70 (0.43, 1.14)	
Percent reduction for MBV compared with IAT	53.8% p=0.029		29.8% p=0.155	

[a]On-treatment adjusted rates and LOS are adjusted for duration of time on treatment (52 days for maribavir, 35.7 days for IAT). [b]Adjusted rates and LOS for the full-study period are adjusted for duration of time in study (132.1 days for maribavir, 92.9 days for IAT).
SD, standard deviation.

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Urine Aspergillus Antigen Detection to Screen for Invasive Aspergillosis in at-Risk Patients Treated for Hematologic Malignancies

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Objectives: Available diagnostics for invasive aspergillosis (IA) require sampling for blood or bronchoalveolar lavage (BAL) fluid, limiting application for screening to detect early disease. Johns Hopkins and MycoMed Technologies have now optimized an ultrasensitive diagnostic enzyme immunoassay called MycoMEIA™ with validation data demonstrating good sensitivity and specificity as an aid to diagnose IA in people with suspected and confirmed IA. Early positivity suggested potential utility as a screening tool in people with high risks.
Methods: To evaluate performance as a screening assay, we tested sequential urine samples obtained from people with hematologic malignancies and/or receipt of allogeneic BMT. Patients had undergone screening with serum Platelia™ GM EIA and BALs were performed with suspicion of IA. Urine samples were collected twice weekly and stored frozen at -80°C. MycoMEIA was tested blind to infection diagnosis, adjudicated using EORTC/MSG definitions. Results of urine tests obtained within the 2-week window prior to clinical diagnosis were considered for screening performance. Results were interpreted using a low index cut-off (0.6) to define positivity in order to optimize sensitivity and negative predictive value (NPV).
Results: 64 screening eligible urine samples from 18 cases (proven/probable IA) and controls were analyzed. Sensitivity for use as a screening test was 64.3% (95% CI: 35–87) for MycoMEIA and 50% (95% CI: 23–77%) for Platelia GM EIA. Assuming a pre-test probability of IA of 10%, MycoMEIA demonstrated an NPV of 92.7% (95% CI: 79–98%). Combined screening with both tests increased sensitivity of IA detection to 80% (95% CI: 52–96%), corresponding to an NPV of 95.7% (95% CI: 85–99%). Urine was positive by MycoMEIA in 5/7 cases with positive serum GM EIA and 7/7 cases with positive BAL GM EIA. MycoMEIA positive cases pre-dated diagnosis established with the aggressive clinical screening by mean 16.4 (range 35 to 2) days.
Conclusions: Urine screening with MycoMEIA performed well to identify early IA in high-risk hematology patients. If both urine MycoMEIA and serum GM EIA were performed during periods of high risk, high NPV may alleviate need for empirical antifungal therapy.

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Immunogenicity of Sars-Cov-2 Vaccination in Hematopoietic Stem Cell Transplant and Chimeric Antigen Receptor T-Cell Therapy Recipients

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Background: Hematopoietic stem cell transplant (HCT) and chimeric antigen receptor-T cell therapy (CAR-T) recipients are at an increased risk of severe coronavirus disease 2019 (COVID-19) and higher mortality with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. We aimed to investigate the immunogenicity of SARS-CoV-2 vaccination in HCT/CAR-T recipients.
Methods: We conducted a single-center prospective longitudinal study including 108 adult HCT/CAR-T patients who received SARS-CoV-2 vaccination (03/2021-07/2021). We excluded 20 patients who were unable to complete the vaccination series, and 88 patients were included in the analysis. Anti-spike protein receptor-binding domain (anti-RBD) and neutralizing antibodies (NAb) have been associated with vaccine efficacy. Anti-RBD and NAb were measured using the Roche Elecsys anti-SARS-CoV-2 S enzyme immunoassay and SARS-CoV-2 Surrogate Virus Neutralization Test assay, respectively. Recent studies have suggested that anti-RBD >100 U/mL and NAb >30% may be associated with protection from COVID-19, and these cutoffs were used. Data were analyzed using SPSS version 21. Bivariate analyses, using the chi-square and t-test, and logistic regression analyses were conducted.
Results: The study included 88 HCT/CAR-T recipients, including allogeneic HCT (n=72), autologous HCT (n=14), and CAR-T (n=2) recipients, who received SARS-CoV-2 vaccination (Pfizer 53%, Moderna 41%, Johnson and Johnson 6%). The median age was 60.5 (19-75) years and 57% were males. Median time since HCT/CAR-T to SARS-CoV-2 vaccination was 14.7 (2.8-113.2) months. Primary hematologic disorders were myeloid (57%), lymphoid (28%), and plasma cell and other disorders (15%). Active graft-vs-host disease (GVHD) was observed in 45% patients (acute 6%, chronic 40%), and active immune suppression included tacrolimus or sirolimus (18%), ruxolitinib (14%), and prednisone (8%). Median anti-RBD was 493 U/mL (0-737,500), and median NAb was 73% (0-90). Adequate anti-RBD (>100 U/mL) and NAb (>30%) were observed in 72% and 74% patients respectively. Vaccination before 12 months post-HCT/CAR-T (anti-RBD: OR 0.22, 95% CI 0.08-0.62, p=0.004; NAb: OR 0.11, 95% CI 0.03-036, p<0.001) and acute GVHD (OR 0.08, 95% CI 0.01-0.80, p=0.031; NAb: OR 0.07, 95% CI 0.01-0.70, p=0.024)

Table 1: Baseline characteristics and immunogenicity of SARS-CoV-2 vaccination in HCT/CAR-T cell therapy recipients

Characteristics	Total (n=88)	Anti-RBD >100 U/mL (n=63)[1]	P value	NAb >30% (n=65)[1]	P value
Age in years, median (range)	60.5 (19-75)	61 (19-75)	0.648	61 (19-75)	0.526
Male gender, n (%)	50 (56.8)	36 (72)	0.922	37 (74)	0.973
Ethnicity, n (%)					
Caucasian	76 (86.4)	54 (71.7)	0.727	55 (72.4)	0.803
African American	5 (5.7)	3 (60)		4 (80)	
Others	7 (7.9)	6 (85.7)		6 (85.7)	
Prior COVID-19 diagnosis, n (%)	4 (4.5)	2 (50)	0.327	2 (50)	0.266
Vaccine, n (%)					
Pfizer	47 (53.4)	35 (74.5)	0.266	27 (75)	0.767
Moderna	36 (40.9)	26 (72.2)		35 (74.5)	
Johnson & Johnson	5 (5.7)	2 (40)		3 (60)	
Hematologic malignancy, n (%)					
Myeloid disorders	50 (56.8)	35 (70)	0.589	35 (70)	0.599
Lymphoid disorders	25 (28.4)	17 (68)		19 (76)	
Plasma cell disorders/others	13 (14.8)	11 (84.6)		11 (84.6)	
Type of cellular therapy, n (%)					
Allogeneic HCT	72 (81.8)	50 (69.4)	0.369	52 (72.2)	0.426
Autologous HCT	14 (15.9)	12 (85.7)		12 (85.7)	
CAR-T	2 (2.3)	1 (50)		1 (50)	
Months since cellular therapy to vaccination, median (range)	14.7 (2.9-113.2)	20.5 (2.8-113.2)	0.006	22.9 (2.8-113.2)	<0.001
Time since cellular therapy, n (%)					
<6 months	17 (19.3)	10 (58.8)	0.010	10 (58.8)	<0.001
6-12 months	24 (27.3)	13 (54.2)		12 (50)	
>12 months	47 (53.4)	40 (85.1)		43 (91.5)	
Anti-RBD (U/mL), median (range)	493 (0-737,500)	1706 (112-737,500)	0.030	1645 (12-737,500)	0.030
NAb (%), median (range)	73 (0-90)	84 (17-90)	<0.001	83 (31-90)	<0.001

Characteristics	Total (n=88)	Anti-RBD >100 U/mL (n=63)[1]	P value	NAb >30% (n=65)[1]	P value
Donor type, n (%)					
Matched sibling	21 (23.9)	16 (76.2)	0.697	17 (81)	0.610
Matched unrelated	28 (31.8)	18 (64.3)		18 (64.3)	
Haploidentical	22 (25)	15 (68.2)		16 (72.7)	
Mismatched unrelated	1 (1.1)	1 (100)		1 (100)	
Autologous/CAR-T	16 (18.2)	13 (81.3)		13 (81.3)	
Graft/cell source, n (%)					
Peripheral blood	68 (77.3)	49 (72.1)	0.858	52 (76.5)	0.305
Bone marrow	20 (22.7)	14 (70)		13 (65)	
GVHD prophylaxis, n (%)					
Tacrolimus	72 (81.8)	50 (69.4)	0.334	52 (72.2)	0.457
Mycophenolate	24 (27.3)	17 (70.8)	0.923	18 (75)	0.882
Post-transplant cyclophosphamide	22 (25)	15 (68.2)	0.682	16 (72.7)	0.889
HCT comorbidity index, n (%)					
0-1	33 (37.5)	26 (78.8)	0.293	26 (78.8)	0.446
2-3	24 (27.3)	15 (62.5)		17 (70.8)	
>3	27 (30.7)	18 (66.7)		18 (66.7)	
NA	4 (4.5)	4 (100)		4 (100)	
Active GVHD (≤2 weeks), n (%)[2]	40 (45.5)	28 (70)	0.763	28 (70)	0.451
Acute GVHD[3]	5 (5.7)	1 (20)	0.008	1 (20)	0.005
Chronic GVHD[4]	35 (39.8)	27 (77.1)	0.348	27 (77.1)	0.569
GVHD treatment, n (%)					
Tacrolimus/sirolimus	16 (18.2)	9 (56.3)	0.133	8 (50)	0.016
Ruxolitinib	12 (13.6)	6 (50)	0.074	7 (58.3)	0.188
Corticosteroids[5]	7 (8)	5 (71.4)	0.992	5 (71.4)	0.879
Ibrutinib	1 (1.1)	1 (100)	0.526	1 (100)	0.550

[1]Row percentages are presented [2]Acute GVHD grading included grade I (n=2), grade II (n=1), and grade III (n=2); [3]Chronic GVHD grading included mid (n=14), moderate (n=15), and severe (n=6); [4]Corticosteroids included 6 of 7 patients receiving >20mg/d prednisone. Abbreviations: SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; COVID-19, coronavirus disease 2019; HCT, hematopoietic stem cell transplant; CAR-T, chimeric antigen receptor-T cell therapy; anti-RBD, anti-spike protein receptor binding domain; NAb, neutralizing antibodies; GVHD, graft-versus-host disease

predicted poor immunogenicity; however, vaccination after 1 year following HCT/CAR-T remained the only independent predictor (anti-RBD: OR 0.28, 95% CI 0.10-0.78, p=0.016, NAb: OR 0.13, 95% CI 0.04-0.44, p=0.001). [Table 1]

Conclusion: HCT/CAR-T recipients showed lower antibody responses to SARS-CoV-2 vaccination. Vaccination after one year was associated with better immunogenicity; however, no difference was noted in individuals vaccinated before or after six months. Further studies are needed to assess vaccine responses after the booster dose and the durability over time.

ORAL ABSTRACT - SESSION G - LATE EFFECTS AND QUALITY IMPROVEMENT

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Patient-Reported Treatment Response in Chronic Graft Vs. Host Disease: Unique Dimension of Clinical Benefit Associated with Failure-Free Survival

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Chronic graft vs. host disease (GVHD) treatment response is routinely assessed using NIH Consensus criteria in clinical trials, and clinician assessment in routine practice. While central to the experience of chronic GVHD manifestations and symptom burden as well as treatment benefit and toxicity, the patient's own assessment of treatment response has not been well studied. We aimed to characterize 6 month patient-reported treatment response, determine which chronic GVHD baseline organ features and changes were associated with patient-reported response, and evaluate which patient-reported quality of life and chronic GVHD symptom burden measures were sensitive to patient-reported response.

A total of 382 subjects from two nationally representative Chronic GVHD Consortium prospective observational studies were included in this analysis, based on available 6 month patient-reported response data. Patient and clinician responses were categorized as improved (inclusive of ordinal scale values of completely gone, very much better, moderately better, a little better) vs. not (about the same, a little worse, moderately worse, very much worse). Comprehensive baseline (patient, disease, transplant, chronic GVHD organ involvement and severity) variables, organ response values at 6 months