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Original Study

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Response to COVID-19 Vaccination Post-CAR T Therapy in Patients With Non-Hodgkin Lymphoma and Multiple Myeloma

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Abstract

This study evaluated SARS-CoV-2 spike-binding IgG antibody levels following COVID-19 vaccination among non-Hodgkin lymphoma and multiple myeloma CAR T therapy recipients. In this retrospective study, we evaluated 104 patients that received CAR T therapy; of those 17 patients were evaluated for antibody spike titers following CAR T therapy. We found that only a minority of non-Hodgkin lymphoma and multiple myeloma patients were able to mount a clinically relevant (>250 IU/mL) antibody response.

COVID-19 adversely affects individuals with cancer. Several studies have found that seroconversion rates among patients with hematologic malignancies are suboptimal when compared to patients without cancer. Patients with non-Hodgkin lymphoma (NHL) and multiple myeloma (MM) are immunocompromised due to impaired humoral and cellular immunity in addition to prescribed immunosuppressive therapy. Chimeric antigen receptor T-cell (CAR T) therapy is now widely used for NHL and MM, but little is known about seroconversion rates after COVID-19 vaccination among these populations. We evaluated SARS-CoV-2 spike-binding IgG antibody levels following COVID-19 vaccination among NHL and MM CAR T therapy recipients. Out of 104 CAR T infusions, 19 patients developed known COVID-19 infection post-CAR T. We tested 17 patients that received CAR T for antibody spike titers post COVID-19 vaccination, only 29 % (n = 5) were able to mount a clinically relevant antibody response (>250 IU/mL).

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Introduction/Background

Coronavirus disease 2019 (COVID-19) adversely affects individuals with cancer. Patients with cancer were initially excluded from COVID-19 vaccine clinical trials. Therefore, this population's response to COVID-19 vaccination is an essential area of research. Several studies have found significantly lower seroconversion rates

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Table 1 Patient Characteristics

Patient Characteristics	
Total, n	104
Evaluable anti-SARS-Cov-2 antibodies	17
Gender, male, n (%)	75 (72)
	13 (76)
Age, median (range)	59.0 (19-79)
	64 (35-77)
Race/ethnicity	
White, n, (%)	86 (83)
	13 (76)
Hispanic or Latino, n (%)	8 (7.7)
African American, n (%)	4 (3.8)
Asian, n (%)	1 (1.0)
Pacific Islander, n (%)	1 (1.0)
American Indian, n (%)	1 (1.0)
Other, n (%)	2 (1.9)
Missing, n (%)	1 (1.0)
BMI, median (range)	26 (17.9-53.8)
	28 (18.3 -34.7)
Diagnosis	
NHL, n (%)	76 (73)
	10 (59)
MM, n (%)	26 (25.0)
	7 (41)
Survival status	
Alive, n (%)	73 (70.)
Deceased, n (%)	31 (30)
COVID-19 pre-CAR T, n (%)	7 (7)
	2 (12)
Days from COVID-19 to CAR T, median (range)	220 (30-265)
	(112-161)
ASCT pre-CAR T	
NHL, n (%)	18 (17)
	4 (40)
MM, n (%)	20 (19)
	6 (86)
Days ASCT to CAR T median (range)	605 (138-4409)
	881 (272-2502)
Vaccinated pre-CAR T, n (%)	4 (4)
	3 (18)
COVID-19 post-CAR T, n (%)	19 (18)
	0
Days from CAR T to COVID-19, median (range)	220 (7-1406)
Days from CAR T to vaccine, median (range)	170 (32-881)
	95 (28-792)
Antibody info for vaccinated, n (%)	17 (16)
% positive for antibody that had a vaccine, n (%)	13 (76)
% negative for antibody that had a vaccine, n (%)	4 (24)
Cell and IgG Count	
WBC, median (range)	3.6×10^4/μL (0.2-28.2)
	5×10^4/μL (1.3-28.2)
ALC, median (range)	0.64×10^4/μL (0.03-870)
	0.73×10^4/μL (0.28-3.43)
CD4, median (range)	110×10^6/μL (4-829)
	137×10^4/μL (34-543)
IgG, median (range)	517 g/L (<300-3611)
	553 g/L (<300-3611)

(*continued on next page*)

Table 1 (*continued*)

Patient Characteristics	
Received IVIG post-CAR T, n (%)	46 (44) 7 (41)
Disease status post-CAR T	
Remission, n (%)	58 (56) 11 (65)
Progression, n (%)	43 (41) 5 (29)
Missing, n (%)	3 (3) 1
Received Rx post-CAR T, n (%)	41 (39) 4 (24%)

Characteristics of the 17 patients with evaluable anti-SARS-Cov-2 antibodies are represented in blue font. Survival status is based on the month/year of September 2021 for the cohort as a whole. Specific survival status for the 17 patients with evaluable anti-SARS-Cov-2 antibodies is discussed in the text as survival follow up was completed at a later date.
Abbreviations: ALC = absolute reticulocyte count; BMI = body mass index; CAR T: chimeric antigen receptor T-cells; IgG = immunoglobulin G; MM = multiple myeloma; N = number of patients; NHL = non-Hodgkin lymphoma; Rx = treatment; WBC = white blood cell count.

in patients with hematologic malignancies compared to their solid tumor counterparts.[1,2] In the CANVAX study, antibody responses were lower in cancer patients compared to controls, irrespective of vaccine type ($P < .001$); however mRNA-1273 was the most immunogenic and patients that received additional vaccine doses displayed increased antibody titers.[3]

Even with increased vaccine availability, COVID-19 continues to mainly threaten vulnerable populations. Among patients with hematologic malignancies, seroconversion rates also appear to be influenced by recent treatment and type of treatment.[4–8] Patients with chronic lymphocytic leukemia who underwent treatment with anti-CD20 antibodies in the preceding 12 months have low to no seroconversion rates following the BNT162b2 mRNA COVID-19 vaccine.[9] Likewise, patients with Waldenström macroglobulinemia have low humoral response after COVID-19 vaccination (either 2 doses of the BNT162b2 or 1 dose of the AZD1222).[10] In addition, patients with multiple myeloma (MM) on active therapy with anti-CD38 regimens and BCMA-targeted therapy have significantly lower seroconversion when compared to patients with MM not on these active therapies.[11]

Less is known about vaccine immunogenicity among patients that have undergone treatment following chimeric antigen receptor T cell (CAR T) therapy. Two studies evaluated seroconversion rates following COVID-19 vaccination in a small number of CAR T therapy recipients and both showed low seroconversion rates (approximately 20%).[12,13] A pooled analysis of SARS-CoV-2 vaccine responses of 236 CAR T recipients revealed a response rate of approximately 28%.[14] This poor seroconversion rate may not be specific to COVID-19 vaccines but other vaccines as well.[15]

Patients with NHL and MM are immunocompromised due to impaired humoral and cellular immunity in addition to immunosuppressive therapy.[11] CAR T therapy is now widely used for NHL and MM, but seroconversion rates are less known after COVID-19 vaccination among these populations. Current national guidelines recommend COVID-19 vaccination be offered to CAR T therapy recipients as early as 3 months postcellular infusion.[16] This study aimed to assess seroconversion rates and mortality following COVID-19 vaccination after CAR T infusion.

Patients and Methods

This retrospective study was conducted at 3 Mayo Clinic sites (Arizona, FL, and MN) looking at NHL and MM patients receiving CAR T therapy from September 2016 to June 2021 (some of which received CAR T prior to the COVID 19 pandemic and vaccination approval on November 12, 2020). We evaluated severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike IgG antibody levels following COVID-19 vaccination among NHL and MM CAR T therapy recipients. Baseline characteristics, date of vaccination(s), number of vaccine doses, and documented COVID-19 infections were obtained from medical records. Laboratory values were obtained at approximately the same time that COVID-19 SARS-CoV-2 antibodies were obtained. All NHL and MM patients who received CAR T therapy at any point and were alive at the time that the first COVID-19 vaccine became commercially available in the United States (November 12, 2020) were eligible for inclusion for antibody response evaluation. This study was approved by the Institutional Review Board of Mayo Clinic.

Testing was performed using the Roche Elecsys anti-SARS-CoV-2 reagent assay (Roche Diagnostics, Mannheim, Germany), which has received Emergency Use Authorization by the U.S. Food and Drug Administration. The assay detects antibodies to the SARS-CoV-2 spike glycoprotein. Antibody levels > 0.8 U/mL were considered positive per our institution's laboratory guidelines. Other publications have defined clinical response according to spike antibody levels as follows: clinically relevant response (>250 IU/mL), partial response (50-250 IU/mL), and no response (<50 IU/mL).[17,18] To align ourselves with recent publications, we also adopted similar cutoffs to render our final results.[19] The date of last follow up for the entire cohort was September 2021. The 17 patients with evalu-

Figure 1 Chronologic description of mortality post-CAR T. It was generated using the swimplot package 1.2.0. in R 4.0.3.

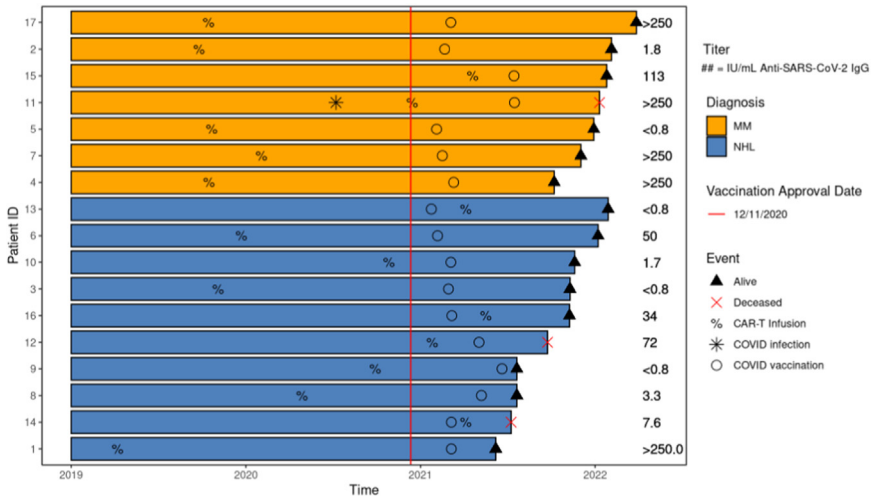

Figure 2 COVID-19 vaccination immunogenicity in patients post-CAR T.

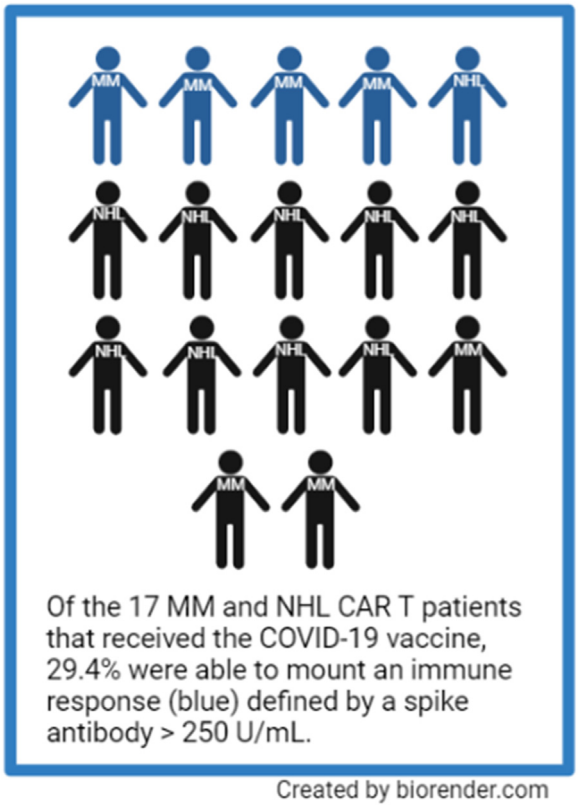

Table 2 Characteristics of 6 Patients Deceased Post-CAR T Following COVID-19 Infection

Patient	Age	Gender	Race	Malignancy	Vaccination Status	Days From CAR to COVID-19
1	73	M	Hispanic	NHL	Unvaccinated	7
2	67	M	White	NHL	Unvaccinated	208
3	62	M	White	NHL	Unvaccinated	101
4	55	M	White	NHL	Unvaccinated	846
5	63	M	White	NHL	Unvaccinated	120
6	63	M	White	NHL	Vaccinated	220

Attribution was not made by the investigator whether COVID-19 was the reason for death instead of a contributing factor.
Abbreviations: F = female; M = male; MM = multiple myeloma NHL = non-Hodgkin lymphoma.

able COVID-19 CoV-2 spike IgG antibody levels were reassessed for survival status update in February of 2022.

Results

We evaluated 104 patients with MM and NHL that received CAR T infusions (Table 1). The median age of patients included in the study was 59.0 years (19-79) and most patients identified themselves as white (n = 86). Within our cohort, 76 patients were diagnosed with NHL and 26 had MM. Twenty-eight percent (n = 29) of individuals that received CAR T therapy were deceased and 72% (n = 75) were alive as of September 2021. Seven patients had COVID-19 infection pre-CAR T and all 7 were alive as of September 2021. Nineteen patients developed COVID-19 infection post-CAR T therapy (13 alive and 6 deceased; 3 patients were known to have received the COVID-19 vaccine; 1 patient had evaluable COVID-19 Co-V2 spike IgG antibody levels). The mortality of those that had COVID-19 infection post-CAR T therapy in our cohort was 31.5%. Of the 13 patients that survived COVID-19 infection, they received CAR T therapy a median of 337 days before COVID-19 infection (range = 54-1406); the 6 patients who died following COVID-19 infection (Table 2) received CAR T therapy a median of 164 days before COVID infection (range = 7-846). All 6 deceased patients did not receive COVID-19 vaccination pre-CAR T therapy (Table 2).

Seventeen CAR T therapy recipients that received 2 doses of the mRNA-1273 or BNT162b2 vaccine or 1 dose for the Ad26.COV2.S vaccine were tested for spike antibody titers post COVID-19 vaccination(s). Baseline characteristics of these 17 patients appeared to be similar to the cohort as a whole with major differences likely secondary to sample size (blue font in Table 1). Among these 17 patients, 7 had MM, and 10 had NHL. Seventy-seven percent (n = 13) had vaccine immunogenicity according to our initial antibody spike values >0.8 U/mL (Figure 2). We found this rate of vaccine immunogenicity to be higher than previously reported immunogenicity after CAR T therapy using a similar cutoff value (57% vaccine immunogenicity, n = 14).[20] Using a positivity cutoff of 50 IU/mL (at least partial response), vaccination immunogenicity in our samples was 47% (n = 8). Using a positivity cutoff of 250 IU/mL (clinically relevant response), vaccination immunogenicity in our samples was 29% (n = 5). The median time from vaccination to antibody testing was 95 days (6-792). Six patients received the mRNA-1273 vaccine, 6 received the BNT162b2 vaccine, 2 received the Ad26.COV2.S vaccine, and 2 were unknown. One patient acquired COVID-19 infection, but this was prior to CAR T infusion. Of patients that received the vaccine, 14 (82%) were alive at the time of updated survival analysis. At the time of data collection tixagevimab/cilgavimab, pre-exposure prophylaxis for COVID-19 infection, was not available, therefore no patients in this cohort received it.

Conclusion

The frequency of vaccination immunogenicity in patients who underwent CAR T therapy among patients with NHL and MM was dependent on positivity cutoff values. Indeed, many studies use differing assays and cutoff values to define seroconversion rates.[4–8,12–14] Approximately one-third of patients that had evaluable antibody spike values following COVID-19 vaccination and CAR T therapy were able to mount an immune response using the strictest criteria for vaccination immunogenicity in our relatively small sample. These findings emphasize that cutoff values need to be better defined. In addition, our results are limited by our small sample size, the retrospective/observational nature of our design, the fact that we did not assess cellular response, and the development of novel COVID-19 variants over time. We also did not evaluate immune response following additional vaccine administration (boosters) which have recently been reported in patients with hematologic malignancies receiving disease-directed therapies.[21,22] These studies report that among those that did not seroconvert after their primary vaccination, 56%- 59% seroconverted after receiving a booster. It should also be noted that the term "immunogenicity" used in this text applies to only to measurable COVID-19 CoV-2 spike IgG antibody levels, but the authors acknowledge that immunogenicity is complex and includes factors that are not measured or reported in this study.

A major limitation of our study is that almost half of our patients (n = 46) received IVIG post CAR T therapy (11 patients were tested for spike antibody titers post COVID-19 vaccination; 4 of which had a detectable antibody spike value at any level), potentially resulting in cross-reactive antibody results as pooled immunoglobulin preparations may contain COVID-19 antibodies from vaccinated healthy donors. It is not known if these patients were receiving active IVIG therapy at the time of antibody assessment. Seropositivity in the United States at the time of this study assessment was reported at 43.3%; accordingly the timing of when studies were performed to quantify antibody response may influence the results.[23] A recent study evaluating response to COVID-19 vaccina-

tion post anti-CD20 therapy in patients with NHL showed that longer time from last exposure to anti-CD20 therapy predicted higher response rates and elevated COVID-19 antibody titer.[4] The ideal time from CAR T therapy to COVID-19 for optimal seropositivity remains to be answered. Interestingly we found that patients in our small sample that died after COVID-19 infection following CAR T therapy did not receive the vaccine prior to CAR T therapy. It should also be noted that whether COVID-19 directly attributed to death among these patients was not made by the investigators. We acknowledge that caution should be taken when interpreting survival in our retrospective review; the relationship of CAR T therapy to the to the pandemic was not fixed, thus some patients who received CAR T therapy years before the pandemic had more opportunity for immune recovery. Another limitation would be time bias since the mortality data on patients who received CAR T more recently (post vaccination approvals) will not be as mature.

Even though patients that receive CAR T have impaired humoral response, COVID-19 vaccination may still benefit this population and perhaps boosters further improve immune reconstitution.[24,25] It should also be noted that because there were no standardized recommendations regarding screening patients for COVID-19 and different investigators had individualized practice, patients chosen for SARS-CoV-2 antibody testing may have introduced selection bias. To better understand the characteristics of the immunologic response against SARS-CoV-2 in patients post-CAR T therapy, more extensive multicenter studies exploring both humoral and cellular immunity will be needed.

Clinical Practice Points

- Approximately one-third of patients with NHL and multiple myeloma following COVID-19 vaccination and CAR T therapy were able to mount an immune response using the strictest criteria for vaccination immunogenicity in our relatively small sample.
- Even though patients that receive CAR T have impaired humoral response, COVID-19 vaccination may still benefit this population and perhaps boosters should follow immune reconstitution.

Ethics Approval and Consent to Participate

This study was approved by the Institutional Review Board of Mayo Clinic.

Consent for Publication

Not applicable.

Availability of Data and Materials

The datasets analyzed during the current study are not publicly available.

Authors' Contributions

JEWN, MI, ACR, PV, HSM, and **JM** contributed to conception and design of the study and acquisition, analysis, or interpretation of data; **JEWN, MI, ACR,** and **JM** drafted the manuscript; **JEWN, BJG, MJM,** and **RM** performed statistical analysis; all authors helped in critical revision of the manuscript for important intellectual content. All authors read and approved the final manuscript.

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