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BRIEF REPORT



Pre-graft vaccination or infection do not decrease COVID-19 infections in recipients of allogeneic stem cell transplantation vaccinated and/or protected by immunotherapy after transplant

Valentin Letaille^a, Amandine Le Bourgeois^a, Thierry Guillaume^{a,b}, Alice Garnier^a, Pierre Peterlin^a, Maxime Jullien^a, Chloe Antier^a, Marie-Christine Béné^c, and Patrice Chevallier^{a,b}

^aHematology Department, Nantes University Hospital, Nantes, France; ^bINSERM UMR1232, CRCINA IRS-UN, University of Nantes, Nantes, France; ^cHematology Biology Department, Nantes University Hospital, Nantes, France

ABSTRACT

The impact of pre-graft COVID-19 vaccinations in donor or recipient as well as pre-graft infection has been studied in 157 adults having received allogeneic stem cell transplantation (Allo-SCT) for various hematological diseases during the delta/omicron waves. We showed here that pre-Allo-SCT COVID-19 vaccination and/or infection do not provide more protection in patients receiving vaccine, immunotherapy or both after transplant. COVID-19 vaccination is and remains of crucial importance after Allo-SCT, reinforcing the recommendation to start COVID-19 vaccination as soon as the third month following the transplant.

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COVID-19; allogeneic; vaccine; infection; BNT162b2; mRNA-1273

Introduction

Just one year after the beginning of the pandemic, in December 2020, mRNA (BNT162b2 and mRNA-1273) and adenovirus vector-based (ChAdOx1 and JNJ-78436735) vaccines became available. This allowed to limit severe forms of COVID-19 infections both in the healthy population¹ and in immunocompromised hosts, including recipients of allogeneic stem cell transplantation (Allo-SCT).^{2–4} In this case, before vaccine (January–December 2020), severe forms of infection and COVID-19-attributable mortality were shown to be around 36% and 25%.³ These rates decrease drastically with the availability of vaccines. For example, during the Delta wave (June–December 2021), Xhaard et al.⁴ showed incidences of 19.6% and 10.8% for severe forms and related deaths, respectively, while during the Omicron wave (January–June 2022) our group showed percentages as lower as 1.4% and 0.5%, respectively.⁵

Patients receiving Allo-SCT were initially vaccinated after transplant, but rapidly both patients and donors could receive vaccine before Allo-SCT. Yet, a potential impact of such pre-graft vaccinations or infections has not been clearly evaluated. Indeed, if previous COVID-19 vaccinations/infections in donors/recipients have been associated in small cohorts with a transfer of specific antibodies or T cells that could react to antigens after Allo-SCT,⁶ or a higher humoral response to early SARS-CoV-2 mRNA vaccination after Allo-SCT,^{7–9} nothing is known on their role on the occurrence of post-Allo-SCT COVID-19 infections, the severity of these infections or the rate of related-deaths. Moreover, in spite of recommendations proposing vaccination programs after 3 months or even 24 months for live attenuated vaccines,¹⁰ their real efficacy in an epidemic context has been poorly explored.¹¹

Here, we wanted to look at the impact in allotransplanted patients of pre-graft COVID-19 vaccination or infection on post-transplant COVID-19 infection occurrence, because no large series have investigated this topic. We assumed that this will have no influence since one might consider that any pre-transplant vaccinations have too much residual effect, given the required immune system ablation that occurs as part of the transplant protocol, and as demonstrated already for several other vaccines.¹⁰

Patients and method

The main objective of the study was to demonstrate if a previous COVID-19 infection and/or vaccination was associated with a lower incidence of COVID-19 infection post-transplant in recipients of allo-SCT. To this avail, the period and numbers of COVID-19 vaccination and previous COVID-19 infection were collected in Nantes University Hospital Hematology Department in Allo-SCT adult recipients transplanted between January 2020 and September 2022. Only patients with a follow-up of at least 3 months post-transplant were retained. Data regarding post-transplant COVID-19 infections were collected from January 2021 (date of access to vaccines) up to July 2023, a period that includes successive waves of COVID-19 infection (mainly Delta and Omicron waves), with personal contact to ensure updated information. Three groups were defined: 1) unvaccinated patients and/or donors without previous COVID-19 infection before Allo-SCT, vaccinated after transplant, 2) patients and/or donors without COVID-19 infection vaccinated before Allo-SCT (with or without vaccine after transplant), and 3) patients

CONTACT Patrice Chevallier ✉ patrice.chevallier@chu-nantes.fr 📧 Service d'Hématologie Clinique, CHU Hotel-Dieu, Place A. Ricordeau, Nantes Cedex 44093, France.

and/or donors with a previous COVID-19 infection (with or without vaccine pre- and post-transplant). The rates of overall and severe forms of COVID-19 infections after Allo-SCT were collected in the whole group and in each subgroup. Severe forms were defined by COVID-19-related hospitalizations (including those in intensive care unit) and/or death. Some patients received tixagevimab and cilgavimab (tix/cil) as preventive treatment after Allo-SCT. The study was approved by the Ethical Review Board of the CHU of Nantes and all patients provided consent for collection of their personal data after transplant.

Univariate and multivariate analyses were performed with adjustments for potential confounding factors using the R software (version 4.0.2). All tests were two-sided and *p* values < 0.05 were considered as indicating a statistically significant association.

Results

A total of 157 patients were enrolled of a median age of 59 y (range: 20–74) and including 91 men. The three sub-groups were comparable in terms of gender, median age, disease, conditioning and donor type, overall post-transplant COVID-19 protection (either vaccine, tix/cil administration or both) but differed in terms of period of transplantation, median time between the graft and the first post-transplant vaccine and median time between Allo-SCT and COVID-19 infection diagnosis (Table 1).

Post-Allo-SCT vaccination, performed for 64.3% of the whole group, reached 100% in group 1 (*n* = 58/58), versus 50% in group 2 (*n* = 31/62) and 32% (*n* = 12/37) in group 3. Tix/cil administration, performed for 47% of the whole group, reached 21% in group 1 (*n* = 12/58), 58% in group 2 (*n* = 36/62) and 70% in group 3 (*n* = 26/37).

Table 1. Patient and group characteristics and COVID-19 infections after allotransplant.

Characteristics	Whole cohort, N = 157	Group 1, N = 58*	Group 2, N = 62**	Group 3, N = 37***	p-value ¹
Gender					0.4
female	66 (42%)	25 (43%)	29 (47%)	12 (32%)	
male	91 (58%)	33 (57%)	33 (53%)	25 (68%)	
Median age : years old (range)	59 (20–74)	55 (20–71)	59 (22–74)	59 (21–72)	0.4
Disease					0.6
Myeloid	122 (78%) ^o	47 (81%)	45 (73%)	30 (81%)	
Lymphoid	31 (20%) ^{oo}	9 (16%)	16 (26%)	6 (16%)	
non-malignant	4 (2%) ^{ooo}	2 (3.4%)	1 (1.6%)	1 (2.7%)	
Conditioning					0.9
Myeloablative	17 (11%)	7 (12%)	5 (8.1%)	5 (14%)	
Reduced-intensity	133 (85%)	48 (83%)	54 (87%)	31 (84%)	
Sequential	7 (4%)	3 (5.2%)	3 (4.8%)	1 (2.7%)	
Donor					0.4
haploidentical	59 (38%)	23 (40%)	22 (35%)	14 (38%)	
Matched unrelated	64 (41%)	24 (41%)	28 (45%)	12 (32%)	
Sibling	31 (20%)	10 (17%)	12 (19%)	9 (24%)	
Cord Blood	1 (0.5%)	1 (1.7%)	0 (0%)	0 (0%)	
9/10 mis-match unrelated	2 (1%)	0 (0%)	0 (0%)	2 (5.4%)	
Date of ASCT	January 2020 to September 2022	January 2020 to September 2021	March 2021 to September 2022	October 2020 to August 2022	<0.001
Tix/cil post ASCT	74 (47%)	12 (21%)	36 (58%)	26 (70%)	<0.001
COVID-19 Vaccine post ASCT	101 (64%)	58 (100%)	31 (50%)	12 (32%)	<0.001
Median time post ASCT : days (range)	168 (27–482)	222 (70–482)	134 (66–347)	157 (27–358)	0.002
If yes, median number of injections (range)	2 (0–3)	3 (2.00–5.00)	2 (1.00–5.00)	2 (1.00–5.00)	<0.001
COVID-19 vaccine and/or Tix/cil	149 (95%)	58 (100%)	57 (92%)	34 (92%)	0.08
COVID-19 infection post ASCT					
Median time of occurrence after ASCT : days (range)	312 (0–1027)	629 (289–1027)	163 (31–402)	217 (0–672)	<0.001
All patients	55 (35%)	24 (41%)	19 (31%)	12 (32%)	0.4
Vaccinated patients post ASCT	37 (37%)	24 (41%)	9 (29%)	4 (33%)	0.49
Severe COVID-19 infection post ASCT					
All patients	14 (8.9%)	6 (10.3%)	7 (11.2%)	1 (2.7%)	0.5
Vaccinated patients post ASCT	12 (11.8%)	6 (10.3%)	5 (16%)	1 (8.3%)	0.66
COVID-19 related death					
All patients	5 (3.2%)	2 (3.4%)	2 (3.2%)	1 (2.7%)	0.97
Vaccinated patients post ASCT	5 (5%)	2 (3.4%)	2 (6.4%)	1 (8.3%)	0.69
Median follow-up : months (IQR)	18.79 (10.43–25.44)	25.93 (23.54–29.80)	14.03 (9.41–16.92)	10.16 (8.03–12.72)	

Note: ¹ comparison of characteristics between the 3 groups (Pearson's Chi-squared test; Kruskal-Wallis rank sum test; Fisher's exact test).

Abbreviations: ASCT : allogeneic stem cell transplantation ; tix/cil : tixagevimab and cilgavimab (Evusheld®) as preventive treatment.

^o: acute myeloid leukemia *n* = 73, including 2 granulocytic sarcoma ; myelodysplastic syndrome (MDS) *n* = 29 ; chronic myelomonocytic leukemia *n* = 5 ; chronic myeloid leukemia *n* = 1 ; Myelofibrosis *n* = 12 ; mixed MDS/myeloproliferative syndrome *n* = 2.

^{oo}: acute lymphoblastic leukemia *n* = 15 ; mixed phenotype acute leukemia *n* = 1 ; non-Hodgkin lymphoma *n* = 6 ; Hodgkin lymphoma *n* = 6 ; T-prolymphocytic leukemia *n* = 3.

^{ooo}: aplastic anemia *n* = 3 ; congenital neutropenia *n* = 1.

*Group 1 : no pre-graft COVID-19 vaccine or infection in both recipients and donors.

**Group 2 : pre-graft COVID-19 vaccine in recipients (R) and/or donors (D) and no pre-graft COVID-19 infection (R vaccinated only *n* = 12 ; D vaccinated only *n* = 7 ; both D and R vaccinated *n* = 43).

***Group 3 : Pre-graft COVID-19 infection in recipients (R) or donor (D), vaccinated or not Infection in R only *n* = 26 (D/R both not vaccinated *n* = 5, D/R both vaccinated *n* = 16, R vaccinated only *n* = 1, D vaccinated only *n* = 4) ; Infection in D only *n* = 9 (D/R both not vaccinated *n* = 1, D/R both vaccinated *n* = 5, R vaccinated only *n* = 3) ; Infection in both D/R *n* = 2 (R vaccinated only *n* = 1, D/R not vaccinated *n* = 1).

in group 3 ($n = 26/37$). Overall, only eight patients did not receive either post-transplant vaccine and/or Tix/cil perfusion, meaning that COVID-19 protection post-transplant was provided in almost all of the patients ($n = 149/157$, 95%, vaccine + no tix/cil $n = 74$; vaccine + tix/cil $n = 27$; No vaccine + tix/cil $n = 48$). Most patients were considered during the delta/omicron waves.

Results are summarized in Tables 1, 2. The first vaccination post-graft was performed at a median of 168 d (range: 27–482), while COVID-19 infection occurred at a median of 312 d (range: 0–1027) post-Allo-SCT.

The overall and severe COVID-19 infection rates were 35% and 9%, respectively, while there were 3% of COVID-related deaths for the whole cohort. However, the rates of severe forms or deaths related to COVID-19 were similar between post-transplant vaccinated and non-vaccinated patients, suggesting that the latter probably occurred in both groups in less protected individuals or that the use of tix/cil in non-vaccinated patients had allowed to comparable protection.

Post-graft COVID-19 infection rates were 41%, 31% and 32% in groups 1, 2 and 3, respectively. Severe post-graft COVID-19 infection and death rates were also similar between the three groups at 10%, 11% and 3%, and at 3%, 3% and 3%, respectively. Considering only patients vaccinated after transplant, all rates were again similar between each group, suggesting that pre-graft vaccination or infection before Allo-SCT do not improve or provide more protection.

By multivariate analysis (Table 3), the only factor associated with the risk of post-transplant COVID-19 infection was the date of transplant (HR 1.003; 95%CI: 1.002–1.004, $p = .02$), reflecting the date of the successive waves of the pandemic. No statistical analysis was performed to identify factor associated with severe form of post-transplant COVID-19 infection because of the small number of events in this case.

Discussion

The aim of the study was to demonstrate if pre-transplant COVID-19 vaccine or infection were able to decrease the rate of post-transplant COVID-19 infections and its severe forms in recipients of Allo-SCT. Our results showed that these factors have no impact on both outcomes, even when considering only post-transplant vaccinated patients. The incidence of post-transplant COVID-19 infections remained high at 35% but in a context of two successive waves (Delta and Omicron) of the pandemic. Indeed, the only factor associated with post-transplant COVID-19 infection was the date of Allo-SCT, reflecting these two successive waves. However, as reported before,^{4,5} severe forms were drastically reduced at 9% with only 3% of COVID-19 related-deaths, suggesting a very efficient protection with post-transplant vaccine or immunotherapy, together with probably less virulent forms of the virus.

Besides post-transplant vaccinations, infections were also reduced using tix/cil as a preventive treatment. This is in accordance with the fact that Tix/cil has been associated with high protection during the Omicron wave in patients not developing humoral response after vaccine.¹² However, due to Omicron mutations, it has become inefficient and has no indication anymore. This straightens the predominant role of vaccine post-transplant.

Indeed, the most important issue remains to provide protection after transplant, because of the removal of immunological memory through conditioning,¹³ with the advantage therefore to stimulate a restoring immune system (even if under therapeutic immunosuppression), by the development not only of a strong humoral response but also a strong SARS-CoV-2 T-cell response, after vaccination.¹⁴

The role of donor vaccination, which is globally an unresolved issue, can also be approached here. In general, information about the efficacy of donor vaccination is limited in the literature, and it is rather not recommended.¹⁰ As mentioned before, previous studies have emphasized a role for donor

Table 2. Post-transplant COVID-19 infections according to pre- and post-graft vaccinal status and pre-graft infection status.

	COVID-19 infections post-allo	Severe COVID-19 infections post-allo	Deaths due to COVID-19 infection
Whole cohort N = 157	55 (35%)	14 (9%)	5 (3.1%)
Vaccination post-allo (V)			
Yes N = 101 (64%)	37 (37%)	12 (12%)	5 (5%)
No N = 56 (36%)	18 (32%)	2 (3.5%)	0
Tix/cil post-allo N = 75 (27 V) (48%)	28 (37%)	5 (6.6%)	0
No Tix/cil post-allo N = 82 (74 V) (52%)	27 (33%)	9 (11%)	5 (6%)
Group 1 N = 58 (no previous vaccine and infection in D/R) (All V)	24 (41%)	6 (10%)	2 (3.4%)
Tix/cil post-allo N = 12 (12 V) (21%)	6 (50%)	1 (8%)	0
No Tix/cil post-allo N = 46 (46 V) (79%)	18 (39%)	5 (11%)	2 (4.3%)
Group 2 N = 62 (no previous inf ±Vaccine in D/R)	19 (31%)	7 (11%)	2 (3.2%)
Vaccination post-allo (V)			
Yes N = 31 (50%)	9 (29%)	5 (16%)	2 (6.4%)
No N = 31 (50%)	10 (32%)	2 (6.4%)	0
Tix/cil post-allo N = 36 (10 V) (58%)	14 (39%)	4 (11%)	2 (5.5%)
No Tix/cil post-allo N = 26 (21 V) (42%)	5 (19%)	3 (11.5%)	0
Group 3 N = 37 (previous inf ±vaccine in D/R)	12 (32%)	1 (3%)	1 (2.7%)
Vaccination post-allo (V)			
Yes N = 12 (32%)	4 (33%)	1 (8%)	1 (8.3%)
No N = 25 (68%)	8 (77%)	0 (0%)	0
Tix/cil post-allo N = 27 (5 V) (73%)	8 (30%)	0 (0%)	0
No Tix/cil post-allo N = 10 (7 V) (27%)	4 (40%)	1 (10%)	1 (10%)

Note: Abbreviations : V : vaccinated after allo, FU : follow-up ; tix/cil : : tixagevimab and cilgavimab (Evusheld®) as preventive treatment.

Table 3. Uni (A) and multivariate (B) analyses.

Covariable	Levels	HR	95%CI	p value (Wald)	p value (likelihood ratio)
A : Univariate analysis					
Date of ASCT*	–	1.003	1.002–1.004	<0.001	<0.001
Group	1	reference			0.001
	2	2.95	1.51–5.76	0.002	
	3	3.53	1.79–6.99	<0.001	
Gender	female	reference			0.42
	male	1.26	0.73–2.16	0.41	
Age	–	0.99	0.97–1.00	0.12	0.17
Disease	myeloid	reference			0.34
	lymphoid	1.07	0.52–2.22	0.85	
	non malignant	2.37	1.08–5.20	0.03	
Conditioning	MAC	reference			0.19
	RIC	0.51	0.28–0.93	0.03	
	Sequential	0.88	0.31–2.44	0.8	
Donor	Haplo	reference			0.47
	MUD	0.94	0.50–1.75	0.84	
	Sibling	1.48	0.76–2.88	0.25	
	9/10 m-MUD	0.00	0.00–0.00	<0.001	
	Cord Blood	3.45	2.19–5.42	<0.001	
Post-ASCT tix/cil	no	reference			<0.001
	yes	2.79	1.56–5.00	0.001	
Post-ASCT COVID-19 vaccination	no	reference			0.81
	yes	0.9	0.34–2.39	0.83	
Covariable	Levels	HR	95%CI	p value	
B : Multivariate analysis					
Date of ASCT*	–	1.003	1.000–1.005	0.02	
Group	1	reference			
	2	1.06	0.34–3.08	0.91	
	3	1.15	0.37–3.57	0.81	
Post-ASCT tix/cil	no	reference			
	yes	1.22	0.49–3.02	0.67	

Note: Abbreviations: ASCT: allogeneic stem cell transplantation. tix/cil : : tixagevimab and cilgavimab (Evusheld®) as preventive treatment; MAC: myeloablative; RIC: reduced-intensity conditioning; haplo: haploidentical; MUD: matched unrelated donor; m-MUD: mis-match MUD.*continuous.

vaccination in terms of higher humoral response after vaccine post-transplant. However, based on our results, which considered infections, severity of infections or related deaths, it seems again that donor vaccination should not be a concern for recipients of Allo-SCT.

Of course, our study has several limitations. Over its retrospective nature, sub-groups were not equivalent in terms of year of vaccine, the number of post-transplant vaccinated patients or the number of Tix/cil administrations. Also, it remains the possibility that asymptomatic COVID-19 infections have occurred in relation with preexisting immunity or less-virulent viruses, while patients may have been engaged in more and less protective activities (e.g., limitation of external contacts, isolation after transplant, etc.) and in variable proportion in each sub-groups. Thus, our results, even if they are expected, have to be confirmed by other teams.

Finally, it is of interest here that some patients received post-Allo-SCT vaccination as early as during the first month post-transplant. These data support and even reinforce the recommendation to start COVID-19 vaccination as soon as 3 months after Allo-SCT, irrespective of concurrent GVHD or use of immunosuppressive medications.¹⁵

In summary, our data, resulting from a large cohort of patients, confirm that an anti-COVID-19 protection is and remains of crucial importance after Allo-SCT. Pre-Allo-SCT

COVID-19 vaccination and/or infection do not provide more protection in the post-Allo-SCT setting. These results also provide interesting knowledge potentially applicable for other types of vaccination in this context of Allo-SCT.

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ORCID

Patrice Chevallier  <http://orcid.org/0000-0003-3142-5581>

Author contributions

VL and PC designed, performed, coordinated the research, analyzed, performed statistical analyses, interpreted the data, and wrote the manuscript.

ALB, TG, AG, PP, MJ, CA, MCB, TG recruited patients, and helped writing the manuscript.

Data statement

The principal investigators (VL+PC) had full access to all the data in the study and took responsibility for the integrity of the data and the accuracy of data analysis.

Ethical standards statement

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008.

Statement of informed consent

Informed consent was obtained from all participants to be included in the study.

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