HIGH SEROCONVERSION RATE AND DELTA NEUTRALIZATION IN PLWHIV VACCINATED WITH BNT162b2

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BACKGROUND

- Vaccination against COVID-19 is an essential weapon to mitigate the consequences of the SARS-CoV-2 pandemic reducing a wide range of COVID-19-related outcomes
- Phase 2/3 studies of BNT162b2 (Pfizer-BioNTech) vaccine shown high efficacy and good tolerance
- This study included PLWHIV in whom data are lacking.

METHODS

- study registered on ClinicalTrial.gov (NCT04844489).
- Inclusion criteria :
  - PLWHIV with a CD4 cell count <500/mm^3
  - viral load (VL) <50 copies/ml
  - stable ART therapy for at least 3 months
  - eligible to COVID-19 vaccination.
- Exclusion criteria :
  - previous known SARS-CoV-2 infection in the 3 last months
  - other vaccination in the 15 days preceding recruitment,
  - known or suspected allergy
  - evocative signs of COVID-19
  - intercurrent infection
  - pregnancy.
- BNT162b2 vaccine : a 2-shots vaccination schedule at an interval of 3 to 6 weeks
- Follow-up : before vaccination (day 0), after shot 1 and before second shot (day 28) and 1 month after the shot 2 (M1).
- Primary endpoint : proportion of patients with a NAb titer greater than 1:10 against the historical strain and the Beta and Delta variants
- Qualitative detection of nucleocapsid protein (anti-N) IgG Abs and quantification of anti-spike RBD IgG Ab (SARS-CoV-2 IgG II Quant, Abbott, Rungis, France) : IgG index ≥ 0.8 indicates a positive serology for anti-N and the cut-off positivity for anti-S is at 7.1 BAU/ml
- A semi-quantitative ELISA assay (NAbs, SARS-CoV-2 Surrogate Virus Neutralization Test, Genscript, USA) based on antibody mediated blockade of ACE-2-Spike protein interaction was performed.

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- Multicenter cohort study of PLWHIV, with a CD4 cell count <500/mm^3 and a viral load <50 copies/ml on stable antiretroviral therapy for at least 3 months.
- **Objectives**: To assess the humoral and cellular responses against SARS-CoV-2 Delta variant after BNT162b2 vaccination in PLWHIV.
- 97 patients enrolled : 85 received 2 vaccine shots (11 previous COVID-19 and 1 premature exit)
- Seroconversion rate at M1 in anti-RBD IgG was 97%
- Neutralizing antibodies (NAbs) capacity improved significantly between D0 and M1
- At M1, NAbs against historical strain, Beta and Delta variants were present in 82%, 77% and 84% patients respectively.

RESULTS

- 97 patients enrolled : characteristics described in the Table 1.
- 85 received 2 vaccine shots (11 previous COVID-19 and 1 premature exit).
- Seroconversion rate in anti-RBD IgG was 97% CI95[90%; 100%] at M1 (figure 1)
- Median (IQR) anti-RBD IgG titer : 0.97 (0.97-5.3) BAU/ml at D0 and 1219 (602-1929) at M1.
- NAbs capacity improved between D0 (15% CI95[8%; 23%]) and M1 (94% CI95[87%; 98%]) with the GenScript assay (p<0.0001)
- At M1, NAbs against historical strain, Beta and Delta variants were present in 82%, 77% and 84% patients respectively.
- Seroconversion rate and median anti-RBD IgG : 91% and 852 BAU/ml in patients with CD4<250/mm^3 (n=13) and 98% and 1270 BAU/ml in patients with CD4>250/mm^3 (n=64) (p=0.39)
- 73% of patients with CD4<250 had NAbs and 97% of those with CD4>250 (p=0.013).
- NAbs against Beta variant were elicited in 50% in CD4<250 and in 81% in CD4>250 (p=0.0292).
- No change in CD4$^+$ or CD8$^+$ T cells count was observed but decrease of CD19$^+$ B cells count was observed (208 ±124 cells/mm3 at D0 vs 188 ±112 cells/mm3 at M1, p<0.01).
- No notable adverse effects or COVID-19 were reported.

CONCLUSIONS

PLWHIV with CD4 counts<500/mm^3 and VL<50 copies/ml have a very good BNT162b2 vaccine response with no impact on CD4 cell count
This is highlighted by a high seroconversion rate and Delta neutralization of these patients after a complete BNT162b2 vaccination schedule.

	Median or number	IQR or %
Age, years	48	39-56
Sex, male	85	87.6%
BMI*	24	22.0-27.1
Other chronic diseases	39	40.2%
- Obesity (BMI > 30 kg/m2)	11	11.3%
- Arterial hypertension	17	17.5%
- Chronic obstructive pulmonary disease	2	2.1%
- Diabetes (1 and 2 types)	2	2.1%
Allergy	5	5.2%
Hemoglobin¶	14.8	13.7-15.7
Lymphocytes¶	1592	1350-1870
ALAT#	25	19-36
ASAT#	24	19-30
Duration HIV infection, years	11.1	7.6-22.2
Past history of OI	47	48.5%
Past history virological failure	31	32.0%
ARV therapy duration, years§	10.4	6.5-17.4
Duration of VL<50 copies/ml, months*	78	28-123
Tritherapy	69	71.1%
Bitherapy	22	22.7%
CD4 cell counts/mm^3	401	303-471
Ratio CD4/CD8	0.7	0.4-0.9

Table 1. Baseline characteristics of PLWHIV vaccinated with BNT162b2 vaccine (n = 97)

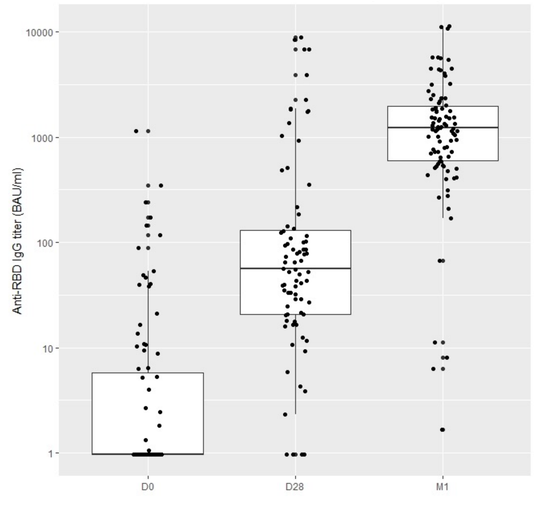

Figure 1. Evolution of anti-RBD IgG levels before and after first and second dose of BNT162b2 vaccine.
Horizontal lines indicate median values; boxes indicate quartiles 1 and 3.