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Humoral Response and Tolerance of Vaccination against SARS-CoV-2 in Adults Senegalese Patients Undergoing Hemodialysis: A Multicenter Prospective Study

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Abstract

Introduction: Following the COVID-19 pandemic, vaccination has been proposed in several countries as the main preventive measure despite very limited data, particularly in dialysis patients. We conducted this study to assess the immunological response to vaccination in Senegalese hemodialysis patients. **Patients and Methods:** We conducted a prospective study, in two dialysis centers in Dakar from March 30th to August 30th, 2021 including patients on hemodialysis for >6 months, vaccinated against SARS-CoV-2 according to the vaccination schedule recommended by WHO. A vaccine response was considered positive when seroconversion was observed after one dose of vaccine. The clinical efficacy of immunization was defined as the absence of new COVID-19 infection in patients who received a complete vaccination. **Results:** Among the 81 patients included in the study, 7.4% had anti-Spike IgM antibodies before their first vaccination. Seroprevalence of IgM antibodies was 38.3% one month after the first vaccine dose (at M1) and 8.6% one month after the second dose (at M4). Anti-Spike IgG antibodies were present in 40.3% of patients before vaccination, in 90.1% at M1, and in 59.7% at M4. Among patients previously infected with SARS-CoV-2, 10.2% had IgM antibodies at M0, 31.6% at M1, and 10.5% at M4 post-vaccination. Similarly, seroprevalences of IgG antibodies in this subgroup were 31.5%, 61.3%, and 50.0% respectively at M0, M1, and M4 post-vaccination. A comparison of se-

roconversion rates between M0 and M4 showed significant differences only for IgG in COVID-19 naive patients. Mean duration in dialysis and the existence of previous COVID-19 infection were associated with patients' vaccinal response after the two doses. Age, gender and the use of immunosuppressive treatment did not influence post-vaccinal antibody production. **Conclusion:** Vaccination against COVID-19 in Senegalese hemodialysis patients induced a low seroconversion rate but it was well tolerated. Moreover, the induced protection was neither strong nor durable, particularly in patients with longer duration in dialysis.

Keywords

SARS-Cov2 Vaccination, Humoral Response, Tolerance, Hemodialysis, Senegal

1. Introduction

Since December 2019, severe acute respiratory syndrome coronavirus (SARS-CoV-2) has caused an unprecedented global health crisis, and African populations were not preserved [1] [2]. With the rapid rise of hospitalizations and deaths, the race for development of safe and effective vaccines became a top priority, and within one year, the first vaccine candidates were approved for use in populations [3] [4]. The immune response to the SARS-CoV-2 involves innate and adaptative immune activation. Most vaccines against COVID-19 elicit antigen-specific responses of lymphocytes and the production of virus-neutralizing antibodies that protect from viral infection [4]. In Senegal, following international guidelines, the COVID-19 immunization campaign started in February 2021, and due to limited doses of vaccine available, it was initially decided to give priority to the most vulnerable groups such as the elderly, diabetics, and patients with chronic kidney disease [5]. This campaign was carried out with great enthusiasm by the health authorities, despite many unanswered questions about the effectiveness of the immune response conferred by vaccines among dialysis patients, the possible side effects, and the best vaccination schedule [2] [5] [6]. This study aimed to assess the effectiveness and clinical tolerance of vaccination against COVID-19 in Senegalese hemodialysis patients.

2. Patients and Methods

2.1. Study Design and Population

We conducted a prospective, multicenter cohort study, over 5 months from March 30, 2021, to August 20, 2021. The study was conducted in hemodialysis centers of Ouakam Military Hospital (HMO) and Idrissa Pouye General Hospital (HOGIP) in Dakar (Senegal). Chronic hemodialysis patients regularly treated in these centers were targeted. We included all patients who had been on dialysis for >6 months, were vaccinated against SARS-CoV-2, and gave their consent.

2.2. Data Collection

A questionnaire was designed and pre-tested by investigators before its use for data collection (see appendix). At inclusion, the following sociodemographic, clinical, and biological data were collected:

- Sociodemographic: age (years), gender (male/female).
- Clinical: duration in dialysis (in months), number of hemodialysis sessions per week, causal nephropathy, history of COVID-19 infection before vaccination; COVID-19 infection after vaccination; adverse events after vaccination; immunosuppressive or antiretroviral therapy.
- Biological: Hepatitis B status (HbsAg); Full blood count (FBC); haemoglobin level (g/dl); calcemia (mg/l); phosphoremia (mg/l); Albuminemia (g/l); Vitamin D level (ng/ml).

Immediate side effects (within 72 hours) were collected during dialysis sessions following injections (first and second doses) and late side effects were collected during routine medical follow-up in hemodialysis.

2.3. Vaccination Scheme and Response Assessment

All selected patients received 2 doses of the ChAdOx1 nCoV-19/AZD1222 vaccine (University of Oxford, AstraZeneca, and Serum Institute of India) 12 weeks apart according to the vaccination schedule recommended by the World Health Organization. We considered as responders all patients who developed antibodies against SARS-CoV-2 Spike protein (titer ≥ 0.8 U/mL) following vaccination. Vaccine protection was judged by the absence of new COVID-19 infection confirmed by RT-PCR in patients who received a complete vaccination schedule. Detection of IgM and IgG anti-spike antibodies by ELISA was performed in all patients at three-time points: before the first dose (M0), one month after the first dose (M1), and one month after the second dose (M4). Data on the existence of post-vaccination COVID-19 disease were collected from dialysis records during the 6 months following vaccination.

2.4. Ethical Considerations

All patients included in the study signed a free and informed consent, and the research protocol was approved by the National Ethics Committee for Health Research (CNERS) at number 00000159/MSAS/CNERS/Sec.

2.5. Statistical Analysis

Data analysis was performed with SPSS (Statistical Package for Social Sciences, version 23).

Data are presented as means and standard deviations for quantitative variables and as proportions for qualitative variables. We compared characteristics of seropositive and seronegative patients using chi-square tests for frequencies and Anova for means. To compare seroconversion rates, we used the McNemar test. Multivariable logistic regression was performed to test associations between the

vaccination response and exposure variables such as age, gender, cause of CKD, duration in dialysis, immunosuppressive treatment, and history of COVID-19 confirmed by RT-PCR. A p-value < 0.05 was considered significant for all statistical tests.

3. Results

Among the 103 targeted hemodialysis patients, we included 81 who were vaccinated against SARS-CoV2 (see Figure 1).

Patients' mean age was 42 +/− 15 years (extremes 18 - 76 years), and the sex ratio was 1.4. The main socio-demographical, clinical, and biological characteristics at baseline (before vaccination) are presented in Table 1. Kidney disease of undetermined etiology and hypertensive nephrosclerosis represented the most frequent causes of end-stage renal disease found respectively in 37% and 33% of patients. About three-quarters (71.6%) of patients were dialyzed 3 × 4 hours/week.

We found a previous COVID-19 pneumonitis (confirmed with RT-PCR) in 23.4% of dialysis patients before vaccination. Two patients were on corticosteroids, and one of them was taking antiretroviral drugs.

Table 1. Socio-demographic and clinical characteristics of patients.

Characteristics	Total population (n = 81)	Responders (n = 48)	Non-responders (n = 33)
Age groups			
<30 years	19 (23.4%)	16 (33.3%)	03 (09.1%)
30 - 59 years	46 (56.8%)	25 (52.1%)	21 (63.6%)
≥60 years	16 (19.8%)	07 (14.6%)	09 (27.3%)
Gender (% Males)	58.0%	58.3%	57.8%
Body mass index (kg/m^2)	25.2 ± 1.9	24.8 ± 3.6	26.1 ± 2.9
Duration on dialysis (months)	26 ± 12.5	20.2 ± 14.3	25.5 ± 12.6*
Dialysis hours/week	10.9 ± 9.3	11.2 ± 7.7	10.5 ± 9.0
Previous COVID-19 infection	19 (23.4%)	12 (22.9%)	08 (24.2%)
Haemoglobin (g/dL)	08.7 ± 2.9	08.3 ± 2.7	09.1 ± 3.1
Leucocytes count (×10^9/L)	05.2 ± 1.9	05.5 ± 1.4	04.5 ± 1.6
Lymphocytes count (×10^9/L)	01.3 ± 0.5	01.4 ± 0.5	01.2 ± 0.7
Platelets count (×10^9/L)	220 ± 70	231 ± 58	214.4 ± 73
Albuminemia (g/L)	33.7 ± 7.8	34.3 ± 4.5	31.9 ± 6.1
Calcemia (mg/l)	86.3 ± 7.7	84.7 ± 9.2	89.7 ± 6.8
Phosphoremia (mg/L)	58.8 ± 18.4	57.0 ± 24.2	90.6 ± 31.1
Vitamin D (ng/mL)	29.6 ± 11.9	33.7 ± 18.7	26.4 ± 17.3
Hepatitis B portage	04 (04.9%)	03 (06.2%)	01 (03.0%)

*significant differences with p < 0.05.

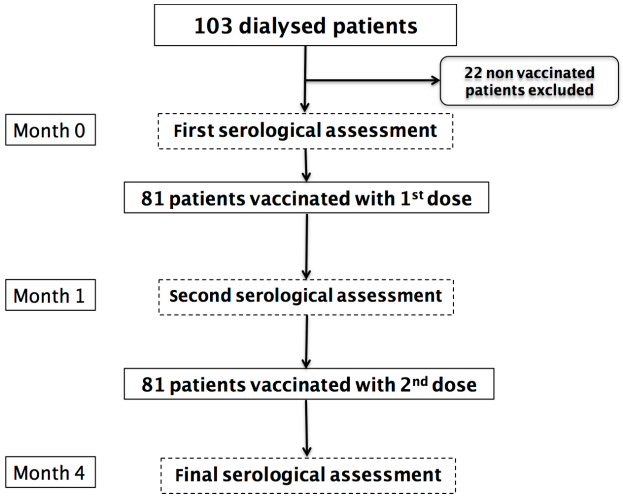

Figure 1. Patients' flow chart.

3.1. Qualitative Determination of Anti-S Antibodies

Among the 81 included patients, 7.4% had detectable anti-Spike IgM antibodies before their first vaccination. The seroprevalence of IgM antibodies was 38.3% one month after the first dose. However, one month after the second dose (at M4), only 8.6% of patients presented IgM anti-S antibodies.

Before vaccination, 40.3% of patients had detectable anti-Spike IgG antibodies, whereas, at M1 and M4, 90.1% and 59.7% of patients presented these antibodies, respectively.

Among the 19 patients infected with SARS-CoV-2 before vaccination, 10.2% had detectable IgM antibodies at M0, then 31.6% at M1 before decreasing rapidly to 10.5% at M4. Similarly, in the COVID-19 naive group, IgM antibodies were absent at M0, raised to 6.4% at M1, and dropped to 1.8% at M4. Following the same trend, 31% of the previously infected patients presented IgG antibodies at M0, 61.3% at M1, and 50% at M4, while in the COVID-19 naive group, 22.8% had detectable anti-Spike IgG at M0, 94.7% at M1 and 89.4% at M4 (**Figure 2**).

3.2. COVID-19 Vaccine's Tolerance

After a complete vaccination regimen, 81.5% of patients reported no adverse events. Only 6.2% of patients developed COVID-19-like pneumonitis within the three following months. Four of these patients had responded to vaccination and were IgG-positive at M4. Vaccination-related events were more frequent in women compared to men (**Table 2**).

3.3. Factors Associated with Vaccinal Response

Mean duration in dialysis > 25 months was associated with a lower risk of IgG seroconversion after two vaccine doses (**Table 3**). The existence of previous COVID-19 infection before vaccination increased the probability of having anti-SARS-CoV-2 IgG after two doses. Patients with previous COVID-19 infection had a 22% higher chance to develop IgG antibodies compared to naive pa-

tients. Male gender and low serum albumin (<40 g/L) were not associated with COVID-19 seroconversion rate. Older age and the use of immunosuppressive therapy did not have a significant influence on the vaccinal response.

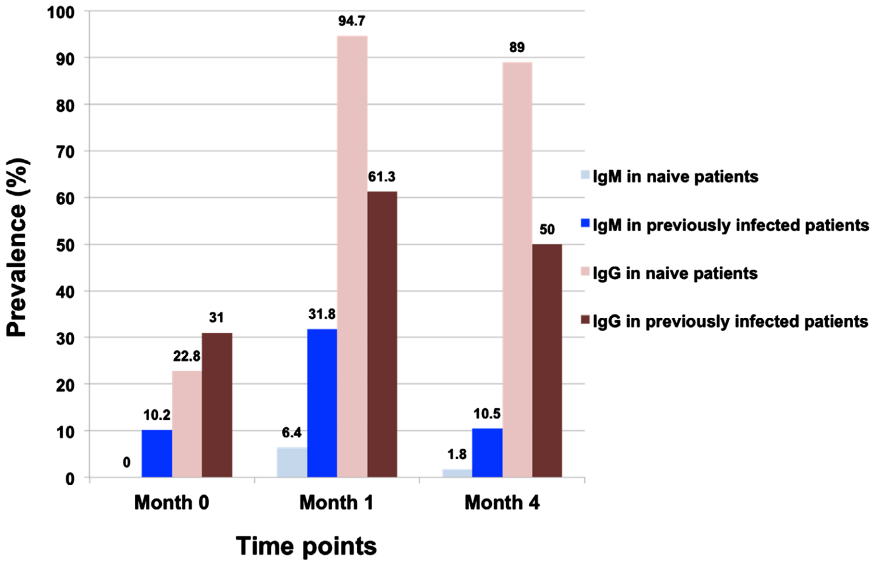

Figure 2. Timely response to SARS-CoV2 vaccination among dialysis patients.

Table 2. Main adverse effects reported in vaccinated patients.

	Immediate reactions				Prolonged reactions			
	Male		Female		Male		Female	
Symptoms	n	%	N	%	n	%	n	%
Allergic reactions	4	4.9%	3	3.7%	0	0.0%	0	0.0%
Headaches	2	2.5%	3	3.7%	0	0.0%	0	0.0%
Myalgia	0	0.0%	2	2.5%	0	0.0%	2	2.5%
Arthralgia	2	2.5%	3	3.7%	0	0.0%	0	0.0%
Fever/chills	5	6.2%	10	12.3%	0	0.0%	0	0.0%
Diarrhea/vomiting	0	0.0%	3	3.7%	0	0.0%	0	0.0%
Chest pain	2	2.5%	5	6.2%	0	0.0%	0	0.0%
Myositis	1	1.2%	4	4.9%	0	0.0%	0	0.0%
Venous thrombosis	0	0.0%	0	0.0%	2	2.5%	0	0.0%

Table 3. Factors associated with IgG seroconversion rate after two vaccine doses.

Symptoms	OR	95% CI	p-value
Age > 50 years	0.73	0.45 - 2.89	0.26
Gender (Male)	1.15	0.12 - 3.11	0.17
Previous COVID-19 infection	1.22	1.08 - 2.65	0.03
Dialysis vintage > 25 months	0.85	0.05 - 0.98	0.04
Albumin < 40 g/L	0.62	0.01 - 3.36	0.58
Use of immunosuppresive drugs	0.09	0.01 - 4.80	0.77

4. Discussion

Vaccination against SARS-CoV-2 triggers the body's production of antibodies that help prevent or attenuate the severity of future infections [7]. However, some subgroups like hemodialysis patients produce fewer antibodies after vaccination due to a blunted immune system response [8]. To our knowledge, the present study is the first that investigated the response to COVID-19 vaccine in African hemodialysis patients.

We found an overall response rate of 59.7% after the two doses of vaccine. A study in Indian hemodialysis patients with similar mean age reported higher response rate (88%) to the AZD1222 vaccine [9]. Also, European and American series assessing responses to SARS-CoV-2 vaccines reported higher response rate despite older patients (aged between 62 and 76 years) [10] [11] [12] [13] [14]. Paradoxically, the relatively younger age of Senegalese patients with CKD [15] did not induce a more vigorous immune response to vaccination as it was previously demonstrated in other populations [16] [17] [18].

The men were predominant in our cohort as what was found in a previous study measuring COVID-19 seroprevalence among Senegalese hemodialysis patients [19]. Several studies evaluating the SARS-CoV-2 vaccine response in dialysis patients described a male predominance and its association with the vaccinal response [20] [21].

Duration in dialysis and existence of a previous COVID-19 infection were the only risk factors of vaccine response identified in our patients. An average duration in hemodialysis > 25 months was associated with a 15% reduction in the capacity of antibody production.

History of COVID-19 infection was documented in 23.4% of our patients and it was associated with a higher seroconversion rate after vaccination. Billany RE *et al.* found that 22% of vaccinated dialysis patients had a previous COVID-19 infection [11]. Also, a study evaluating the response to both BNT162b2 and mRNA-1273 vaccines in the US reported that 20% of dialysis patients had a previous COVID-19 infection [22]. However, their postvaccinal IgG antibody levels were not significantly different from the naïve patients [22]. Previously infected patients might have developed immunity but the magnitude and the durability of this protection are variable [23] [24]. Many data suggest that patients receiving vaccination after a previous SARS-CoV-2 infection present the best antibody response [25]. This is consistent with many studies that identified duration in dialysis as a risk factor associated with a faster immunity decline as well as the type of dialysis, male sex, type of vaccine, and use of immunosuppressive drugs [23] [26] [27]. Other studies identified younger age, less comorbidity, O blood group, and high hemoglobin and albumin levels as factors positively associated with seroconversion [22]. However, such parameters were not significantly associated with vaccinal response in our patients.

In this study, we observed a weak and rapidly waning humoral response after the first and second doses of the vaccine. In fact, the overall seroconversion rates

were not statistically different between M0 and M4 except for the subgroup of COVID-19 naïve patients. The small sample size and the presence of anti-S IgG antibodies in a high proportion of patients (40.3%) before the first dose could explain this difference. The discrepancies observed between studies on vaccinal response to COVID-19 might be linked to different sample sizes and vaccination schemes used in each dialysis centre [26].

In this study, 6.2% of patients developed confirmed COVID-19 infections despite a full vaccination scheme. The occurrence of COVID-19 cases in vaccinated hemodialysis patients raises the issue of the appropriate number and interval between vaccine doses as rapidly waning immunity enhances the risk of new infections, especially in patients with comorbidities. Several observational studies [28] [29] have described a decrease in antibody levels from the third month following the second dose, which led to the administration of booster doses after four months in hemodialysis patients instead of six months as recommended in the general population, combined with monitoring of antibody levels to assess the need for another booster shot [30] [31]. Furthermore, Dimeglio C *et al.* found that anti-S antibody levels after the third dose of vaccine were much higher and more sustained, with less inter-individual variability, compared to fewer doses [32].

Currently, based on post-vaccination surveillance data, many countries have adopted the third and fourth boosters for high-risk groups like hemodialysis patients [33].

The present study presents some limitations due to the qualitative nature of the SARS-CoV-2 antibody assay with did not allow a quantitative follow-up of antibody titers to assess the magnitude of the response to vaccination. Also, the small sample size reduced the study power and we might have missed some significant relationships between vaccine response and some risk factors. However, it showed preliminary results about the potential efficacy and rationale of COVID-19 vaccination in Senegalese hemodialysis patients.

5. Conclusion

Following the high impact of the COVID-19 pandemic on health systems and guidelines for vaccination, this study is the first to assess the efficacy and tolerance of mRNA vaccine in a cohort of African hemodialysis patients. Results found that this vaccine offered a rapid humoral immune response. However, it was of small magnitude and short-lasting. Also, the only significant determinant of vaccination response was patients' duration in hemodialysis. Additional boost doses could help maintain good antibody levels among patients. Further studies with quantitative dosage of neutralizing antibodies are necessary to assess the COVID-19 vaccination's efficacy in African hemodialysis patients and provide recommendations more adapted to this population.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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Appendix

Data collection form.