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COVID-19 vaccination in chronic hemodialysis patients in Senegal: prevalence and side effects

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ABSTRACT

Introduction: The new coronavirus, identified in late 2019 in China, is characterized by higher mortality among chronic hemodialysis patients. The vaccination is the best approach to fighting infection after barrier measures have failed.

Objectives: The aims of this study were to determine the prevalence of COVID-19 vaccination among chronic hemodialysis patients in Senegal, to describe side effects and to assess the factors associated with their occurrence.

Patients and Methods: This was a cross-sectional, multicenter, descriptive, and analytical study from April 1 to July 1, 2021, including all chronic hemodialysis patients in the target centers who had received at least one dose of COVID-19 vaccine and consented to participate in the study.

Results: Of 535 patients surveyed, 367 were included, representing a prevalence of COVID-19 vaccination of 68.6%. The median age of patients was 51 years, with extremes of 20 and 100 years, and a sex ratio of 1.08. The chAdOx1-S [recombinant] vaccine (Astra-Zeneca) was the most widely administered (98.4%). Side effects were noted in 52.6% of patients. They were dominated by local effects (65.6%), followed by influenza-like symptoms (60.8%). Other side effects were digestive (11.1%), neurological (9%), ENT (5.3%) and cardiovascular (4.8%). No deaths were recorded. Coagulation of the extracorporeal circuit during the four sessions following vaccination, despite anticoagulation of the circuit, was observed in one patient. Age <50, diabetes, and anticoagulation were associated with side effects in the bivariate analysis. In the multivariate analysis, age <50 years was a risk factor, while anticoagulation had a protective effect.

Conclusion: Vaccination against COVID-19 is well tolerated among chronic hemodialysis patients in Senegal.

Implication for health policy/practice/research/medical education:
In a cross-sectional, multicenter, descriptive, and analytical study on a group of chronic hemodialysis patients, we found vaccination against COVID-19 in chronic hemodialysis patients is well tolerated. Side effects were moderate, with spontaneous resolution of the symptoms.

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Introduction

A new coronavirus was identified in late 2019 as the cause of pneumonia in the Chinese city of Wuhan in Hubei province (1). It spread rapidly leading to an epidemic around China before being classified as a pandemic since March 11, 2020 by the World Health Organization (WHO) (2). People with comorbidities like chronic hemodialysis patients, have an increased risk of contracting the disease and developing severe forms (3). In addition to being a group at very high risk of infection, these patients have a higher mortality rate than the general population, which can exceed 20% depending on the study (4). Barrier

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restrictions such as self-isolation and social distancing are not applicable to these patients, who need to visit the hemodialysis center 3 times a week and are generally surrounded by other patients and medical staff (5). After the failure of the first preventive measures, including confinement and barrier measures, vaccination against SARS-CoV-2 has become indispensable, reducing the severity of infection and hospitalization rates (6). In order to make better use of this precious resource, many countries have developed vaccination program strategies during the first wave of the pandemic, targeting high-risk individuals such as chronic hemodialysis patients (7). However, due to the lack of evidence for the safety and efficacy of SARS-CoV-2 vaccines in these patients, the medical community has developed a form of hesitancy regarding the use of vaccines (2).

Objectives

The main objective of the present study was to determine the prevalence of COVID-19 vaccination in chronic hemodialysis patients in Senegal, and the secondary objectives were to describe side effects and to assess factors associated with their occurrence.

Patients and Methods

Type, site and study period

This study is a multicenter, cross-sectional study conducted during the period from April 1 to July 1, 2021. Participants were recruited from seven hemodialysis units in Dakar (Aristide le Dantec Hospital and university center, Idrissa Pouye Hospital in Grand Yoff, Pikine Hospital, Roi Bedouin Hospital, Dakar hemodialysis center, Alioune Badara Cissé center, Ouakam military hospital) and hemodialysis units in the regions of Matam, Kaolack and Diourbel (Figure 1).

Patients

Patients undergoing chronic hemodialysis for more than three months, over 18 years of age, who had received at least one dose of the COVID-19 vaccine available during the study period and who consented to participate in this study were included. Patients with psychiatric pathologies or dementia were not included. The principles of patient anonymity and confidentiality were respected.

Study design

Data were collected using a standardized questionnaire for all patients, with multiple choice questions previously validated during a pre-test carried out on 35 patients in the Annex hemodialysis unit at Aristide Le Dantec hospital. The questions were as direct as possible, with limited answers to yes/no (closed questions). Data collection was carried out during an interview with the patients. It was completed by the nephrologists in charge of the centers, using the patients' dialysis medical files. For included patients, the following parameters were studied; sociodemographic, clinical, and therapeutic characteristics, history of COVID-19 infection, associated symptoms, type of vaccine and side effects associated with COVID-19 vaccine administration.

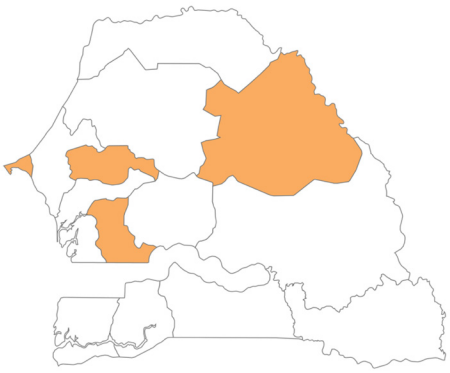

Figure 1. Situation of hemodialysis units.

Regarding post-vaccination side effects, participants were asked to choose from symptoms they had experienced in the week following vaccination. This part was designed to answer questions on general, site-specific, musculoskeletal, gastrointestinal, psychological, neurological, endocrine, cardiovascular, respiratory, urinary and allergic symptoms. The final section asked when the symptoms appeared.

Statistical analysis

Data collection and analysis were carried out using Sphinx Plus version 5 and SPSS (Statistical Product for Social Science) version 20.0 respectively. Quantitative data were presented as means and standard deviations (if the distribution was normal) and as median and interquartile ranges (if the distribution was abnormal). Qualitative data were presented as numbers and percentages.

In bivariate analysis, data from the two patient groups (patients with side effects and those without) were compared on quantitative parameters using the T-test, and on qualitative parameters using the χ^2 test. All test results were two-tailed and assessed at the 5% significance level ($P \leq 0.05$).

For multivariate analysis, the binary logistic regression method ("side effects": Yes/No) was conducted. All variables with a P value ≤ 0.25 were retained to model of occurrence of side effects. Top-down modeling was conducted. Adjusted odds ratios (95% CI) were determined for each variable retained in the final model. Models were compared by Akaike information criterion (AIC) and the quality of adjustment by the Hosmer test.

Results

Prevalence of COVID-19 vaccination

Of the 535 chronic hemodialysis patients surveyed, 367 were included, indicating a prevalence of 68.6% of patients vaccinated against COVID-19 (Figure 2).

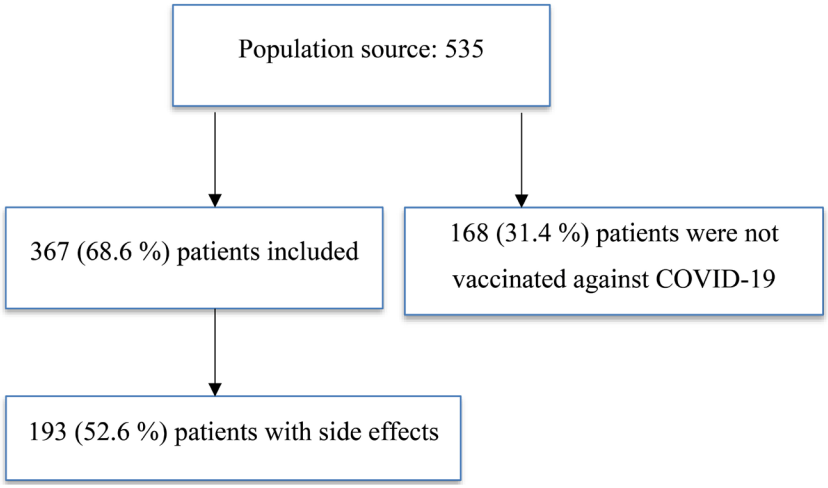

Figure 2. Flowchart of the study.

Patient characteristics during the survey

The median age (interquartile range, IQR) of patients (48% female) was 51 (39- 62) years. The median time on dialysis was 44.5 (25-73) months. Initial kidney disease was undetermined in 43.7%. Comorbidities were dominated by hypertension (83.3%), obesity (14.2%) and diabetes (11.4%). Patient characteristics are shown in Table 1.

Post-vaccination side effects

Side effects were noted in 52.6% patients. They were dominated by local effects (65.6%) (Figure 3). Meanwhile, the different signs are reported in Table 2, as no deaths were recorded. Coagulation of the extracorporeal circuit was observed in one patient during the four sessions following vaccination, despite anticoagulation of the circuit. Cellulitis was noted on day 4 post-vaccination, requiring short-term hospitalization (Figure 4). Side effects occurred mainly the day after vaccination in 56% of cases (Figure 5).

Factors associated with side effects

Our study showed, age <50 years, diabetes and anticoagulation were significantly associated with the occurrence of side effects after COVID-19 vaccination in the bivariate analysis (Table 3). In the multivariate analysis, anticoagulation had a beneficial effect (adjusted hazard ratio: 0.15; $P=0.025$; 95% CI: 0.03-0.79), while younger age (adjusted hazard ratio: 2.6; $P<0.0001$; 95% CI: 1.5-4.3) had an aggravating effect (Table 4).

Discussion

The COVID-19 vaccine is an essential step in the fight against the pandemic (8). In chronic hemodialysis patients, the immune response after vaccination is comparable to that of controls (9). It is associated with a reduced case-fatality rate (10). Vaccination against COVID-19 is therefore essential in this high-risk group to reduce mortality and hospitalization rates. However, there is a lack of data on the safety of the COVID-19 vaccine in these patients. This study aimed to determine the prevalence of COVID-19 vaccination in chronic hemodialysis patients in Senegal, to describe the detailed profile of side effects of the vaccine, and to analyze the factors associated with their occurrence. To our knowledge, this is the first study

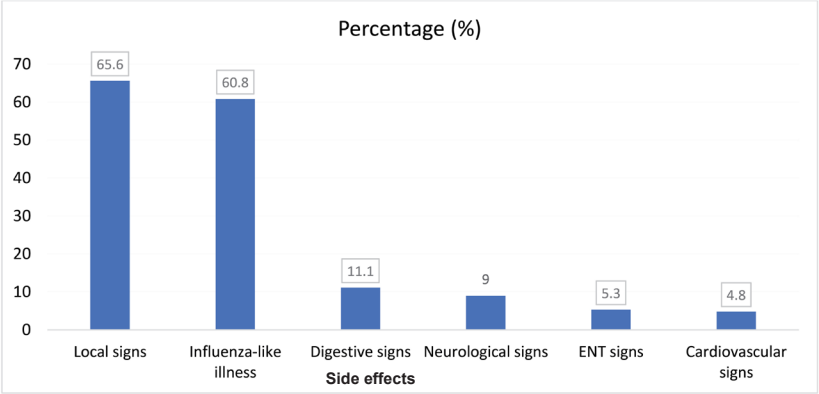

Figure 3. Distribution of side effects observed from 193 patients.

Table 1. Patient characteristics during the survey (n = 367)

Variables	No. (%) or median (IQR) (n = 367)
Age (year)	51 (39-62)
Men	191 (52)
Marital status	
Single	59 (16.08)
Married	246 (67.04)
Widowed	59 (16.08)
Not available	3 (0.8)
Profession	
No profession	236 (64.31)
Informal sector	62 (16.89)
Formal sector	66 (18.80)
Education level	
Illiterate	126 (34.3)
Primary school	43 (11.7)
High school	113 (30.8)
University	85 (23.2)
Time on dialysis (months)	44.5 (25 - 73)
Initial kidney disease	
Undetermined	160 (43.7)
Nephropathy attributed to hypertension	128 (34.9)
Diabetic kidney disease	37 (10.7)
ADPKD	23 (6.3)
Others	19 (4.4)
History of COVID-19	47 (12.8)
Comorbidities	
Hypertension	324 (88.3)
Diabetes	52 (14.2)
Obesity	42 (11.4)
Heart disease	29 (7.9)
Vascular access	
AVF	287 (78.2)
Tunneled catheter	73 (19.8)
Simple catheter	7 (1.91)
Drugs	
Erythropoietin	193 (53.4)
Iron	143 (39)
Anticoagulation (LMWH; VKA)	17 (4.6)
Antibiotics	3 (0.8)
Corticosteroids	2 (0.5)
Vaccination against COVID-19	367 (68.6)
chAdOx1-S [recombinant]	361 (98.4)
COVID-19 Vaccine BIBP	4 (1.1)
Tozinameran	2 (0.5)

AVF: Arteriovenous fistula, ADPKD: Autosomal dominant polycystic kidney disease, LMWH: Low molecular weight heparin, VKA: Vitamin K antagonists.

Table 2. Distribution of different signs observed from 193 patients

Variables	Number (%), n = 193
General signs	
Asthenia	72 (37.3)
Fever	59 (30.6)
Headaches	48 (24.9)
Myalgias	41 (21.2)
Arthralgias	38 (19.7)
Chills	12 (6.2)
Sweats	6 (3.1)
Local signs	
Pain at injection site	98 (50.8)
Heavy limb	33 (17.1)
Swelling at the injection site	24 (12.4)
Pruritus at injection site	9 (4.7)
Post-vaccination cellulitis	2 (1.0)
Hemorrhage at injection site	1 (0.5)
Erythema at injection site	1 (0.5)
Digestive signs	
Abdominal pain	11 (5.7)
Vomiting	10 (5.2)
Diarrhea	7 (3.6)
Nausea	6 (3.1)
Cardiovascular signs	
Palpitations	6 (3.1)
Angina pain	3 (1.6)
Arterial hypotension	2 (1.0)
Neurological signs	
Dizziness	6 (3.1)
Sleep disorders	6 (3.1)
Paraparesis	1 (0.5)
Cramps	1 (0.5)
Hypersensitivity	1 (0.5)
ENT signs	
Rhinorrhea	5 (2.6)
Ageusia	4 (2.1)
Anosmia	2 (1.0)
Dysphonia	1 (0.5)

to address this subject in Senegalese chronic hemodialysis patients.

In our study, we noted a 68.6% prevalence of COVID-19 vaccination among chronic hemodialysis patients. These results are in contrast to those found in a French study, where the prevalence was 80% (11). A study conducted in Egypt by Nassar et al found a prevalence of 91.6% (12). The low-prevalence in our study could be explained by the poor communication during the pandemic, also by the lack of confidence and the absence of adequate information concerning the safety and efficacy of COVID-19 vaccines (13).

Alongside to the contextual determinants already highlighted and more difficulties in accessing health and vaccination services, African countries generally demonstrate both a lower perception of the risk of

Figure 4. Cellulitis at day 4 post-vaccination in a 29-year-old chronic hemodialysis patient at Aristide le Dantec hospital.

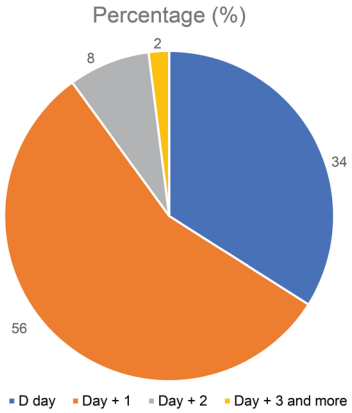

Figure 5. Time to onset of side effects from the 193 patients.

spreading COVID-19 infection and low levels of health literacy (14).

Furthermore, our study was conducted during a phase of the pandemic in which there appeared to be a decrease in the number of confirmed cases, leading people to believe that the virus has been eliminated. This may also have led to a hesitancy to vaccinate, explaining the low prevalence (14).

Table 3. Results of bivariate analysis of factors associated with the occurrence of side effects

Socio-demographic data		Did you experience any side effects in the week following vaccination?		All[a] (N= 367)	*P* value[b]
		Yes[a] (n = 193)	No[a] (n = 174)		
Sex	Men	92 (47.7)	99 (56.9)	191 (52.0)	0.08
	Women	101(52.3)	75 (43.1)	176 (48.0)	
Marital status	Single	32 (16.8)	27 (15.8)	59 (16.3)	0.27
	Married	134 (70.2)	111 (64.9)	245 (67.7)	
	Widowed/Divorced	25 (13.1)	33 (19.3)	58 (16.0)	
Education level	Primary school	23 (11.9)	20 (11.5)	43 (11.7)	0.42
	High school	55 (28.5)	58 (33.3)	113 (30.8)	
	University	42 (21.8)	43 (24.7)	85 (23.2)	
	Coranic	3 (1.6)	5 (2.9)	8 (2.2)	
	Illeterate	70 (36.3)	48 (27.6)	118 (32.2)	
Profession	No profession	121 (62.7)	114 (65.5)	235 (64.0)	0.85
	Formal sector	39 (20.2)	32 (18.4)	71 (19.3)	
	Informal sector	33 (17.1)	28 (16.1)	61 (16.6)	
Socioeconomic status	Low	75 (39.1)	64 (36.8)	139 (38.0)	0.78
	Medium	97 (50.5)	94 (54.0)	191 (52,2)	
	High	20 (10.4)	16 (9.2)	36 (9.8)	
Age <50 years		103 (53.4)	69 (39.9)	172 (47.0)	0,01
Time on dialysis >90 months		42 (21.8)	26 (14.9)	68 (18.5)	0.09
Hypercholesterolemia		14 (8.4)	15 (9.6)	29 (9.0)	0.70
Diabetes		11 (5.7)	31 (17.9)	42 (11.5)	<0.001
Hypertension		169 (88.0)	155 (89.6)	324 (88.8)	0.63
Anemia (Hb <8 g/dL)		43 (25.6)	41 (31.1)	84 (28.0)	0.30
Anticoagulation (VKA; DOA)		4 (2.1)	13 (7.6)	17 (4.7)	0.01
Heart failure (LVEF <55)		15 (9.4)	14 (10.1)	29 (9.7)	0.82
Obesity		27 (14.1)	25 (15.0)	52 (14.5)	0.82
Albuminemi <35 g/L		16 (16.2)	6 (9.2)	22 (13.4)	0.20
Kt/V <1.4		24 (24.5)	27 (27.8)	51 (26.2)	0.60

Hb: Hemoglobin; VKA: Vitamin K antagonists; DOA: Direct oral anticoagulants; LVEF: Left ventricular systolic ejection fraction.
[a] Number (%); [b] Fisher or χ^2 test.

Table 4. Results of multivariate analysis of factors associated with the occurrence of side effects

Did you experience any side effects in the week following vaccination?	*P* value	HR Adjusted	95% CI (HR)	
			Lower	Upper
Age <50 years	< 0.0001	2.618	1.578	4.344
Anticoagulation (VKA; DOA)	0.025	0.159	0.032	0.790

VKA: Vitamin K antagonists, DOA: Direct oral anticoagulants, HR: hazard ratio.
After adjustment for age, sex, time on dialysis, diabetes, anticoagulation and serum albumin < 35 g/L.

In addition, there are enormous fantasized risks surrounding vaccination in general, and COVID-19 in particular. Among the most frequently alleged, vaccination is the cause of debilitating conditions, autism, multiple sclerosis, and diabetes. Others support the idea that vaccines contain contaminants (mercury, aluminum), or that there is a conspiracy to hide the truth about the catastrophic side effects of vaccines (15,16).

In our study, side effects were noted in 52.6% of the patients. They were dominated by local effects, particularly pain at the injection site and influenza-like symptoms, noted in 65.6% and 60.8% respectively. They are not specific to vaccination against COVID-19 and are almost universally observed in most other vaccinations (17). Sakhi et al (18) in France reported similar results, with pain at the injection site, fever and transient aches and pains, generally resolving with symptomatic treatment. In a prospective observational and monocentric study performed in Poland, Polewska et al (19) noted that 59.6% and 61.4% of chronic dialysis patients had at least one local site reaction within 7 days respectively after first and second injection of BTN162b2. They also found that 15,9% of the patients involved in their study had systemic reactions included fatigue, muscle pains, joint pains and headaches. These results are similar with those reported in our study (19).

Gastrointestinal symptoms were reported (11.1%) in our study, dominated by abdominal pain (5.7%) and vomiting (5.2%). In the study by Nassar et al (12), these symptoms were dominated by anorexia (25.4%) and abdominal pain (7.5%). In general, the majority of gastrointestinal tract-related side effects observed after COVID-19 vaccination are non-life-threatening and transient (20).

The most commonly reported neuropsychiatric symptoms in our patients were dizziness (3.1%) and sleep disturbance (3.1%). Impaired sleep quality was reported in 10.65% of healthcare workers after COVID19 vaccination (21). It is essential to determine whether COVID-19 vaccination induces neuropsychiatric disorders (22).

In this study, age <50 years was a risk factor associated to the occurrence of side effects. This could be explained by the fact that elderly subjects report fewer side effects, most likely due to a greater pain tolerance and/or a weakening of innate immune defense mechanisms. It is supported by the fact that the elderly has lower systemic concentrations of IL-10, IL-6, and CRP after vaccination, which may contribute to their tendency to report fewer systemic side effects (19).

Study Highlights

What is the current knowledge?

• Chronic hemodialysis patients have a high risk of COVID-19 infection and a higher mortality rate than the general population
• There is a lack of evidence about safety and efficacy of SARS-CoV-2 vaccines in these patients.

What is new here?

• Vaccination against COVID-19 in chronic hemodialysis patients is well tolerated.
• Side effects are moderate and dominated by local effects.

Conclusion

Our study has shown that vaccination against COVID-19 in chronic hemodialysis patients is well tolerated. Side effects were moderate, with spontaneous resolution of the symptoms. The benefits of vaccination outweigh the risks of non-vaccination. Therefore, the different actors must do their best to ensure maximum protection for chronic hemodialysis patients.

Acknowledgments

We would like to thank all the medical and paramedical staff at the targeted hemodialysis centers for facilitating data collection.

Limitations of the study

Our study has the advantage of being multicentric, with a considerable study population. However, some limitations must be noted. Firstly, we used self-reported data, which may lead to bias in information, such as inconsistent reporting by participants. Secondly, we assessed only short-term side effects occurring within one week of vaccination. The medium- and long-term effects of the vaccine are still unknown. Finally, patients received different types of COVID-19 vaccine, making it impossible to conclude on the side effects of a specific type. This study must be complemented by a study about the efficacy of this vaccination among the patients in our context.

Authors' contribution

Conceptualization: Ibrahima Lyra Sarr, Moustapha Faye, Bacary Bâ, Maria Faye, Ahmed Tall Lemrabott, El hadji Fary Kâ.

Data curation: Ibrahima Lyra Sarr, Baratou Coundoul.
Formal analysis: Ibrahima Lyra Sarr, Niakhaleen Keita, Moustapha Faye
Investigation: Ibrahima Lyra Sarr, Moustapha Faye.
Methodology: Ibrahima Lyra Sarr, Moustapha Faye, El hadji Fary Kâ.
Supervision: Maria Faye, Ahmed Tall Lemrabott, Sidy Mohamed Seck, El hadji Fary Kâ.
Writing-original draft: Ibrahima Lyra Sarr, Niakhaleen Keita, Moustapha Faye.
Writing-review and editing: Bacary Bâ, Baratou Coundoul, Maria Faye, Ahmed Tall Lemrabott, Sidy Mohamed Seck, El hadji Fary Kâ.

Conflicts of interest

The authors declare that they have no conflict of interests.

Ethical issues

This research was conducted in accordance with the principles of the Declaration of Helsinki and received approval from our university. Furthermore, all participants provided written informed consent.

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