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Vaccine Response against Hepatitis B Virus in Patients with Chronic Kidney Failure Not on Dialysis and Factors Associated with Poor Response

Mauria Gilga Ibobi[1,2*], Jile Florient Mimiesse[1,2], Gaël Honal Mahoungou[1,2], Jhonsial Joseph Molami Bovane[2], Bénedicte Niotsebe Ahombo[1,2], Bienvenu Hostaud Atipo Ibara[1,2], Mardoché Pérès Motoula[1,2], Marlyse Ngalessami Mouakosso[2], Arnaud Mongo-Onkouo[1,2], Ngala Itoua Ngaporo[1,2], Rody Stéphane Ngami[1,2], Clausina Mikolélé Ahoui Apendi[1,2], Blaise Irénée Atipo Ibara[1,2]

[1]Faculty of Health Sciences, Marien Ngouabi University, Brazzaville, Republic of the Congo
[2]Brazzaville University Hospital Center, Brazzaville, Republic of the Congo
Email: *mauriaibobi@gmail.com

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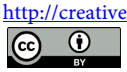

Abstract

Objective: To study the vaccine response to the hepatitis B virus vaccine in patients with chronic kidney disease (CKD) and identify factors associated with poor vaccine response. **Materials and Methods:** This longitudinal and analytical study was conducted over a two-year period, from January 1, 2022, to December 31, 2023. The research was carried out in the nephrology outpatient department of Brazzaville University Hospital. All patients aged 18 years or older, of any sex, with stage 4 or 5 CKD—regardless of etiology—who provided informed consent were included. **Results:** A total of 61 consenting patients were enrolled in the study, comprising 42 men and 19 women, resulting in a sex ratio of 2.21. The mean age was 50.36 years ± 14.07, ranging from 21 to 79 years. The most prevalent comorbidities were hypertension (63.3%, n = 38), diabetes (39.3%, n = 24), obesity (26.2%, n = 16), and heart disease (24.5%, n = 15). Nearly 70% of patients exhibited a positive vaccine response, with 23% (n = 14) classified as good responders and 46% (n = 28) as poor responders. Among male participants, 74% (n = 31) were highly immunized. Chronic kidney disease (CKD) duration exceeding five years and CKD stage 5 were statistically associated with poor or absent vaccine response (p: 0.0195; p: 0.0150). Diabetes mellitus was the only comorbidity linked to poor or absent vaccine response (OR: 1.11 [0.34 - 3.59], p: 0.0615). **Conclusion:** A high rate of good

vaccine response was observed in our study population. CKD duration exceeding 5 years and stage 5 CKD were associated with poor or absent response to vaccination. Diabetes mellitus was identified as the sole factor associated with poor vaccine response.

Keywords

Hepatitis B Virus, Vaccine Response, Chronic Kidney Disease

1. Introduction

Infection with hepatitis B virus (HBV) and its complications constitute a major public health concern. According to the World Health Organization (WHO), more than 2 billion individuals worldwide are infected with HBV, including 350 million chronic carriers. This pandemic accounts for 15% - 25% of deaths secondary to cirrhosis and hepatocellular carcinoma [1] [2]. The prevalence of HBV is high across Africa, particularly in sub-Saharan regions. For example, a 2013 study in Niamey reported a frequency of 15.4% [3], while seroprevalence is 9.3% in Gabon [4]. In Congo, several studies have indicated HBV seroprevalence rates ranging from 5% to 20% [5] [6]. HBV infections are common and present a significant threat to patients with chronic kidney disease (CKD). Some reports indicate that 50% - 60% of patients with chronic renal failure may become chronic HBV carriers due to impaired immune systems, and may also increase the risk of HBV transmission to other hemodialysis patients, healthcare personnel, and family members [7]. A recent study in Saudi Arabia reported a HBV prevalence of 8% among patients with chronic renal failure [8]. In Benin, HBV seroprevalence is 14% in patients receiving care for chronic renal failure [9]. Luma *et al.* in Cameroon reported a prevalence of 10.6% among renal failure patients [10]. In healthy individuals, HBV infection can be prevented or controlled by the host immune response (anti-HBs) directed against the major surface antigen (HBsAg), either spontaneously or through vaccination [11]. However, in patients with renal failure, HBV vaccination is less effective than in healthy subjects [12], as these patients exhibit lower seroconversion rates and reduced antibody titers [13]. Furthermore, antibody titers decline more rapidly over time, and certain factors negatively affect HBV seroconversion in this population [14] [15]. In Congo, data regarding the HBV vaccine response in patients with CKD remain unavailable. The aim of our study was to evaluate the vaccine response in CKD patients and to identify factors associated with this response.

2. Patients and Methods

This was a longitudinal and analytical study conducted over a two-year period, from January 1, 2022 to December 31, 2023. The study was carried out in the outpatient nephrology department of the University Hospital Center of Brazzaville

(CHU-B). Biological analyses were performed at the laboratory of the National Reference Center for Sickle Cell Disease. The study included all patients aged 18 years or older, of either sex, diagnosed with stage 4 or 5 chronic kidney disease of any etiology, who tested negative for hepatitis B virus markers (AgHbs, anti-Hbc antibody, anti-Hbs antibody), and who provided informed consent. Patients were excluded if they had chronic liver disease, were undergoing chronic hemodialysis, were being followed for HIV infection or a malignant tumor, had prior exposure to HBV, or if informed consent was not obtained. Further exclusions applied to patients scheduled to receive immunosuppressive therapy, those who withdrew their informed consent during the study, those lost to follow-up during the study period, or for whom sample collection could not be performed.

The variables examined included sociodemographic factors (age; sex; marital status; educational level; occupational status), clinical characteristics (disease duration; etiology of CKD; comorbidity), biological parameters (anti-HBs antibody level), and factors related to vaccine response (frequency of response, non-responders, low responders, good responders). Patients were classified into three groups

-Group 1: non-responders (anti-Hbs antibody titer <10 IU/ml - 100 IU/ml).

-Group 2: weak immune responders (anti-HBs Ab titer: 10 IU/ml - 100 IU/ml).

-Group 3: good immune responders (anti-Hbs antibody titer >1100 IU/ml).

Data analysis and processing were conducted using Epi Info version 7.2 and Microsoft Office Excel 2021. Quantitative variables were reported as mean with standard deviation or as median with the first and third quartile. Comparisons between means were performed using analysis of variance (ANOVA) and the Chi-square test. Differences were considered statistically significant when the p-value was less than or equal to 0.05 (<5%).

3. Results

During our study, 61 patients were included, of whom 42 were men and 19 were women; the sex ratio was 2.21. The average age was 50.36 years ±14.07, with extremes of 21 years and 79 years. The most represented age group was that of patients aged between 40 and 59 years.

The majority of patients had a low socio-economic level (42.62%), were civil servants (31.15%), and were married (40.98%). Table 1 shows the distribution of patients according to socio-economic level.

The majority of patients had arterial hypertension (63.33%), followed by diabetes and obesity with (39.34%) and obesity (26.23%), respectively. Table 2 shows the distribution of patients according to their comorbidities.

Regarding the duration of CKD, it was less than 5 years in 63.9% of patients (n = 39) and more than 5 years in 36.1% of cases (n = 22).

On the etiological level, diabetes in 27.87% (n = 17), arterial hypertension 26.23% (n = 16), and CKD 22.95% (n = 14) were respectively the most frequently found etiologies (Table 3).

Table 1. Distribution of patients according to profession, marital status and socio-economic level.

	n	%
Profession		
Student	3	5
Civil servant	19	31.1
Prive	11	18
Retirement	12	19.7
Unemployed	16	26.2
Marital status		
Single	20	32.8
Married	25	41
Common-law union	10	16.4
Widower	6	9.8
Socio-economic level		
Low	26	42.6
Medium	23	37.7
High	12	19.7

Table 2. Distribution of patients according to their comorbidities.

	Yes		No	
	N	%	N	%
HTA	38	63.3	23	83.7
Cardiopathy	15	24.6	46	75.4
Diabetes	24	39.3	37	60.7
Obesity	16	26.2	45	73.8
AVC	9	14.7	52	85.3
VHC	4	6.6	57	93.4

Table 3. Distribution according to the etiologies of CKD.

	N	%
Diabetes	17	27.87
GNC	14	22.95
HTA	16	26.23
INDETERMINE	3	4.92
NTIC	7	11.48
PKRD	1	1.64
Renal artery stenosis	1	1.64
VIH	2	3.28

GNC: chronic glomerulonephritis; PKRD: dominant polycystic kidney disease.

Regarding the vaccine response, 69% of patients demonstrated a positive response to vaccination; of these, 23% were classified as good responders and 46% as low responders. Good vaccine response was associated with male sex, age below 60 years, chronic kidney disease (CKD) stage 4 compared to stage 5, and a duration of renal insufficiency of less than 5 years. The table below (**Table 4**) presents the univariate analysis of factors associated with vaccine response.

Table 4. Univariate analysis of sex, age group, stage of CKD and duration of CKD according to the vaccine response.

	Anti-HBs antibody level						
	Good responders		Low responders		Non-responders		P-value
	n	%	n	%	n	%	
SEX							
Masculine	10	23.81	21	50	11	26.19	0.293
Feminine	4	21.05	7	36.85	8	42.1	
AGE GROUP							
>60 years	4	22.22	7	38.89	7	38.89	0.6093
<60 years old	10	23.26	21	48.84	12	27.91	
IRC STAGE							
stage 5	3	12	12	48	10	4	**0.015**
stage 4	11	30.56	16	44.44	9	25	
SENIORITY IRC							
>5 years	7	31.82	10	45.45	5	22.73	**0.0195**
<5 years	7	17.95	18	46.15	14	35.9	

4. Discussion

In our study, the mean age was 50.36 ± 14.07 years, with a range from 21 to 79 years. Most patients were between 40 and 59 years old. This may be due to the fact that renal failure often affects young adults. Our findings are consistent with those reported by Hafouf K. in 2022 in Morocco [16]. Boumansour *et al.* in 2014 in Algeria [17] observed a higher mean age than in our cohort, which may be attributable to differences in sample size.

We observed a marked predominance of males, with a *sex-ratio* of 2.21. Similarly, Boumansour *et al.* (2014) in Algeria and Hafouf K. (2022) in Morocco also reported male predominance [16] [17]. These findings suggest that chronic kidney disease (CKD) may affect males to a greater extent.

Hypertension (HTA) and diabetes were the most common comorbidities, identified in 63.33% and 39.3% of cases, respectively. Both hypertension and diabetes are conditions that can progress to complications, notably renal failure. Our findings are consistent with those reported by Hafouf K. in 2022 in Morocco [16], who observed diabetes followed by hypertension as the most frequent comorbidities.

This trend can be attributed to increased behavioral changes in our context, where the population adopts a Western-style diet that is poorly regulated, characterized by excessive intake of sugar, salt, and polyunsaturated fats, along with other habits such as tobacco and alcohol consumption. Additionally, there is inadequate disease control and poor therapeutic follow-up among most patients in this group, primarily due to low socioeconomic status or ancestral beliefs that lead them to seek care from traditional healers [18].

In our study, 69% of participants exhibited a positive vaccine response, with 23% classified as good responders. According to the literature, patients with advanced CKD demonstrate a diminished response to vaccination, particularly to thymus-dependent antigens (*i.e.*, hepatitis B, diphtheria, or tetanus), whereas the immune response to thymus-independent antigens (*i.e.*, pneumococcal disease) appears to be normal. A defect in the interaction between B and T lymphocytes, rather than in intrinsic B lymphocytes, has been noted. Our results are lower than those reported by Fabrizi *et al.* in 2020 in Italy, Hafouf K. in 2022 in Morocco, Tong N *et al.* in 2005, and Surquin *et al.* in 2010 [15] [16] [19] [20]. This discrepancy may be attributable to the type of vaccine used, as well as differences in study type and population.

The male population in our study was highly immunized. Nevertheless, no statistically significant association was observed. Literature data indicate that women exhibit a better response to the vaccine than men, and that the post-vaccination decline of anti-HBs antibodies occurs more rapidly in men than in women. Hormonal factors and lifestyle are likely responsible for this difference. Similarly, Stevens *et al.* (2017), DaRoza *et al.* (1984), and Pereira *et al.* (2003) [21]-[23] did not report any statistical association.

Our study found that the proportion of both good and poor responders was significantly higher among patients under 60 years of age. This finding may be attributed to the more rapid decline of antibody levels over time and to factors such as age, sex, obesity, nutrition, and tobacco use, all of which negatively affect seroconversion in patients with CKD [15]. Immunity evolves with age; neither changing the vaccine type nor adding a booster dose enhances immunity in the elderly. Advancing age leads to decreased IFNɣ production, inhibited macrophage proliferation, diminished function, and impaired cytotoxic capacity of NK cells [24]. However, there was no statistically significant association. Our results are consistent with those reported by Al Saran *et al.* in Saudi Arabia in 2014, Ibrahim *et al.* in Egypt in 2006, Harford *et al.* in 2016, and Fabrizi *et al.* in Italy in 2011 [14] [25]-[27], who likewise did not observe a statistical association with age.

Diabetes was statistically associated with a poor vaccine response. Several hypotheses have been proposed regarding the impaired response to the HBV vaccine in individuals with diabetes, including a reduced number of circulating T helper cells, a lower CD4-CD8 lymphocyte ratio, diminished lymphocyte blastogenesis [28], and the presence of the DR3, DR7, and DQ2 alleles of human leukocyte antigens (HLA) among diabetic patients [29]. In contrast, heart disease, obesity, and

stroke were not statistically linked to vaccine response. These findings may suggest an immunodeficiency in CKD patients with certain comorbidities.

The majority of patients who responded to vaccination were at stage 4 chronic kidney disease (CKD). A statistically significant association was found between CKD stage and vaccine response. According to KDIGO guidelines, hepatitis B vaccination is recommended for patients with renal insufficiency (GFR < 30 ml/min/1.73 m^2) at stages 4 - 5 CKD, and serological testing should be used to confirm the vaccine response. At the advanced stage 5 CKD, seroconversion rates are lower; consequently, HBV-antibody responses to the hepatitis B virus are weaker and less sustained [30] [31].

Patients with renal insufficiency of less than 5 years responded mostly to vaccination, and a significant influence of the duration of CKD was demonstrated.

In our study, logistic regression analysis did not identify any factors associated with the vaccine response in patients with CKD. This finding may be attributable to the small sample size, which could introduce bias. Therefore, a larger sample size is necessary to more accurately evaluate these factors.

Diabetes and hypertension represented risk factors for poor vaccine response, with a statistical link found for diabetes. There was no statistical link concerning hypertension.

Hafouk K. in Morocco in 2022 found advanced age, male sex, overweight, hypoalbuminemia, co-infection C, diabetes, EPO deficiency, and chronic bio-incompatibility as factors associated with poor vaccine efficacy [16].

Conflicts of Interest

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

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