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**Original Research Article** 

# Serodiagnosis of Hepatitis B Surface Antigen and Anti Hepatitis C Virus among Hemodialysis Patients in Khartoum State- Sudan

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Abstract: Background: Hepatitis B virus (HBV) is a hepatotropic virus that can establish a persistent and chronic infection in humans through immune energy. Hepatitis C virus (HCV) is a hepatotropic RNA virus that causes progressive liver damage. In hemodialysis (HD), blood is removed from the patient with needles and plastic tubing and pumped past the dialysis membrane. Poisons and toxins cross the dialysis membrane into the dialysate, which is then discarded, and the blood is returned to the patient. **Objectives**: The study aimed to detect HBsAg and anti-HCV in HD patients and the control group. *Methods*: A retrospective case-control, a hospital-based study was carried out on 110 participants 60 HD patients and 50 control, 60 males and 50 females, ages between 20 -39 years 27 participants and ages between 40-59 years 32 participants and ages more than 60 51 participants, ELISA method was used to detect HBsAg and anti-HCV in HD patients and control sera, the study was carried out during the period from August 2021 to January 2022. Results: In this study, the overall prevalence of HBV infection among HD patients and the control group was 26.3% (2/110), and among HD patients was 45 % (27/60), while it was 4% (2/50) among the control group any non -HD patient, co-patient, hospital staff and the overall prevalence of HCV was 1,8 % (2/110) and it was 3.3% (2/60) among the HD patients, 0% (0/50) among the control group. There was a significant association between HBV infection and HD (P value 0.019). Conclusions: The prevalence of HBV among HD patients was very high (45%). The results emphasize the need to carry out proactive tasks for early diagnosis by using highly sensitive and specific methods such as PCR technique, treatment of infected individuals, and vaccinating those with non-protective anti-HB antibodies to reduce morbidity and mortality in HD patients.

Keywords: HBV, HCV, Surface Antigen, Hemodialysis, Serodiagnosis, Sudan.

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#### **INTRODUCTION**

Hepatitis B virus (HBV) and hepatitis C virus (HCV) infections are blood-borne viruses, an important cause of morbidity and mortality among hemodialysis (HD) patients, and create problems in the management of patients in the renal dialysis units [1]. HBV and HCV are responsible for most chronic liver diseases worldwide and are transmitted by parenteral, sexual, and vertical routes [2]. Vertical transmission (VT) is the primary route of transmission of viral hepatitis in children, ranging from 1–28% with HBV, and 3–15%

with HCV [3]. Perinatal transmission of hepatitis viruses can be determined by the timing of infection and infectious routes during pregnancy, delivery, and parturition [4]. According to its effects on the liver; HBV was considered a hepatotoxic virus, that is; can establish persistent and chronic infections in humans through immune energy such as chronic hepatitis, liver cirrhosis, and hepatocellular carcinoma [5]. Recently, 3.5% of the global population are chronically infected with HBV, besides that, more than 240 million individuals worldwide are infected with chronic HBV [6, 7]. The genomic -structure of HBV consists of a double-stranded

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DNA, eight genotypes were identified and labeled from A to H and four sub-genotypes have been described [8]. The main serological markers of HBV are HB surface antigen (HBsAg), anti-HBs, HBe Ag and anti-HBe, and anti-HBc IgM and IgG [9]. HCV is another hepatotropic RNA virus that causes progressive liver damage, which might result in liver cirrhosis and hepatocellular carcinoma [10]. Globally, between 64 and 103 million people are chronically infected [11]. The relative importance of the two most common exposures associated with the transmission of HCV; is blood transfusion and intravenous drug use (IVDU) [12]. HCV exhibits great genetic diversity and is classified into 7 genotypes (GTs), with varied geographic prevalence [13]. Infection with HCV is associated with increased mortality among HD patients [14]. The transmission of HCV comes through the sharing of personal hygiene products that have come into contact with the blood of someone infected with HCV [15]. In hemodialysis, blood is removed from the patient with needles and plastic tubing and pumped past the dialysis membrane. Poisons and toxins cross the dialysis membrane into the dialysate, which is then discarded, and the blood is returned to the patient, both are further promoted by the characteristic immunological dysfunction that develops in renal failure and interferes with the patient's ability to eliminate these viruses [16, 17]. Increased risk of nosocomial infection by HBV or HCV in patients on HD has been attributed to impaired cellular immunity and blood transfusions [18]. There was no vaccine available for clinical use in HCV. DNA vaccines have some advantages such as producing feasibility and generating intensive cellular and humoral immune responses, variety of elements have been implicated in adjusting the effectiveness of DNA vaccines such as host, target antigenic region, primeboost approaches, presence or absence of adjuvant, dosage and, which then produces immunization schedule which can be utilized to boost immunization outcomes [19, 20]. Hepatitis B (Hep B) vaccine is produced using recombinant DNA technology. A plasmid containing the gene for hepatitis B surface antigen (HBsAg) is inserted into common baker's yeast HBsAg, and two single-antigen vaccines, Engerix-B, and Recombivax HB® are conjugated with aluminum The vaccine is typically given to children in 3-dose 6 series at age 0 months, at 1 to 2 months, and at to 18 months [21].

## **MATERIALS AND METHODS**

**Study Design:** A retrospective observational case-control study.

**Study Duration**: The study was carried out from August- 2021 to January – 2022.

#### **Study Area**

A hospital-based study was carried out in a hemodialysis center at Parents Charitable Hospital located in Omdurman city, the center contains 15 hemodialysis machines, and receives 20 - 30 patients daily; coming from inside and outside Khartoum state.

#### **Study Population**

110 participants 60 HD patients and 50 control, 60 males and 50 females, ages between 20 -39 years 27 participants, and ages between 40-59 years 32 participants, and ages more than 60 51 participants.

#### Sample Size

The overall sample size was 110 participants, specified as, 60/110 hemodialysis patients (case group) and 50/110 control individuals.

**Sampling Technique**: A nonprobability, convenience sampling technique was used in this study to select the case and control groups.

#### Data Collection Tools

Blood sample: From each participant; 5 ml of blood specimen was collected in a plain container, after clotting of the blood all specimens were centrifuged for 5 minutes and the serum was separated in another plain container and then labeled with serial number for case and control and stored at -20°C until further analyses. Before performing the ELISA test all samples were transferred to plain Eppendorf cups and labeled with specific labeled numbers as case or control. A written questionnaire was used to collect demographic and clinical data from each participant after verbal consent was taken.

#### Ethical Approval

This study was conducted after getting approval from the informed consent, Research committed to Alfajr College and Medical Laboratory Science Program. Verbal consent was taken from all participants before taking the blood samples.

#### Data Analysis

Data were analyzed through SPSS version 23. The difference between categorical variables was tested using. Pearson Chi-square test. The P value was considered significant when it is less than 0.05, to find out the Correlation between the case and control and the study variables; Independent Samples T Test was used; a *P value* less than 0.05 is significant.

### RESULTS

The overall number of participants in this study was 110, 60 of them were HD patients in who case group, and 50 were considered as the control group, 54.5 % of all participants were males (60/110), while the females were 45.5 % (50/110). The majority of the participants age more than 60 years 46.4% (51/110). The mean age was 52.1 years. 85.5% (94/110) of the participant's residences in Omdurman around the HD center. 47.3 % (52/110) of the studied population had a history of hypertension while D. M occurrence was 8.2% (9/110), and 9.1% (10/110) of the studied population had both

Hypertension and D.M. Since the age of the majority occurred in the range of more than 60 years, the HBV vaccine was limited to 84.5% (93/110) of all participants who were non-vaccinated against HBV. In our study, 46.4% (51/110) of the HD patients had a history of HD at a duration between 1-10 years. 59.1% (65/110) of them stayed at home without work, and 37.3% (41/110) were educated at the university level (Table 1). The overall prevalence of HBV infection among case and control groups was 26.3% (29/110), and among the case (HD patients) the prevalence was 45% (27/60), HBV vaccinated was 15.5% (17/110) and non-vaccinated was 84.5% (93/110), and among the control group was 4%(2/50). 68.9 % (20/29) of these infected individuals were males and 62% had a history of hypertension (18/29). Also, 72.4% (21/29) of them had not taken the HBV vaccine and 47% (8/17) of vaccinated individuals had a positive result for HBV showing that the immune HBV vaccine remains response toward the unsatisfactory. None of the infected participants had a history of jaundice or needle injury (0/29). According to these results; there was a significant association between HBV infection and history of hypertension (P. value 0.049), HBV vaccine (P. value 0.019), and duration of dialysis (P. value 0.000), and there was needle injury (P. value 0.012). On the other hand, the

insignificant association between HBV infection and gender (P. value 0.057), age (P. value 0.222), and history of jaundice (P. value 0.222) (Table 2). In this study, the prevalence of HCV was 1.8% (2/110) among the case and control groups, and it was 3.3% (2/60) among the HD patient and 0% (0/50) among the control group. The two infected individuals were males, their age more than 60 years, had a history of hypertension, none of them was vaccinated against HBV, and both had a duration of HD of more than one year, also they had no history of jaundice or needle injury. Besides the low prevalence of HCV infection compared with HBV infection in our setting, there was no significant association between HCV infection and gender, age, duration of HD, hypertension, jaundice, and needle injury. In this study, no co-infection with HBV and HCV was detected (Table 3). In this study, there was a significant difference between the prevalence of HBV infection in the case (HD patients) (45%) and the control group (4%) (P value 0.000). Also, there was a significant difference between HBV infection and HBV vaccine in HD patients, and the control group (P value 0.000). But there was no significant difference between case & control in the gender, age, and HCV infection (P. value 0.212, 0.626, 0,196) respectively (Table 4).

Туре	Variable	Frequency	Percent%	
Gender	Male	60	54.5	
	Female	50	45.5	
	Total	110	100	
Age	20-39	27	24.5	
	40-59	32	29.1	
	More than 60	51	46.4	
	Total	110	100	
Residence	Omdurman	94	85.5	
	Khartoum	7	6.4	
	Out Khartoum state	9	8.2	
	Total	110	100	
Chronic disease	Hypertension	52	47.3	
	D.M	9	8.2	
	Hypertension and D.M	10	9.1	
	No	39	35.5	
	Total	110	100	
HBV vaccine	Yes	17	15.5	
	No	93	84.5	
	Total	110	100	
Duration of HD	Less than one year	9	8.2	
	1 - 10 years	51	46.4	
	More than 10 years	1	0.9	
	No	49	44.5	
	Total	110	100	
Occupation	Worker	37	33.6	
-	Employee	8	7.3	
	No work	65	59.1	
	Total	110	100	
Education Level	Un literate	35	31.8	
	Primary	34	30.9	
	University	41	37.3	
	Total	110	100	

Table 1: Demographic Data of the Participants

Туре	Variable	HBV infection				Total	P. value
		Negative	Percent	Positive	Percent		
Gender	Male	40	49.4%	20	68.9%	60	
	Female	41	50.6%	9	31%	50	0.057
	Total	81	100%	29	100%	110	
Age	20-39	20	24.7%	7	24.1%	27	
	40-59	21	25.9%	11	37.9%	32	
	More than 60	40	49.4%	11	37.9%	51	0.222
	Total	81	100%	29	100%	110	
Chronic disease	Hypertension	34	41.9%	18	22.2%	52	
	D.M	8	9.9%	1	1.2%	9	
	Hypertension and D.M	6	7.4%	4	4.9%	10	0.049
	No	33	40.7%	6	7.4%	39	
	Total	81	100%	29	100%	110	
HBV vaccine	Yes	9	52.9%	8	47%	17	
	No	72	77.4%	21	22%	93	0.019
	Total	81	100%	29	100%	110	
Duration of dialysis	Less than one year	6	7.4%	3	10.3%	9	
	1- 10 year	28	34.6%	23	79.3%	51	
	More than 10	0	0	1	3.44%	1	0.000
	No	47	58%	2	6.8%	49	
	Total	81	100%	29	100%	110	
Jaundice	No	79	97.5%	27	93.1%	106	
	Yes	2	2.5%	2	6.8%	4	0.228
	Total	81	100%	29	100%	110	
Needle injury	No	81	100%	27	93.1%	108	
	Yes	0	0	2	6.8%	2	0.012
	Total	81	100%	29	100%	110	

Table 2: Association between HBV Infection and Study- Variables

Table 3: Association between HCV Infection and Study- Variables

Туре	Variable	HBV infection and Study- variables			Total	P value	
		Negative	Percent	Positive	Percent		
Gender	Male	58	53.7%	2	100%	60	
	Female	50	46/3%	0	0	50	0.193
	Total	108	100%	2	100%	110	
Age	20-39	27	25%	0	0	27	
	40-59	32	29.6%	0	0	32	
	More than 60	49	45.4%	2	100%	51	0.308
	Total	108	100%	2	100%	110	
Chronic disease	Hypertension	50	46/3%	2	100%	52	
	D.M	9	8.3%	0	0	9	
	Hypertension and D.M	10	9.2%	0	0	10	
	No	39	36.1%	0	0	39	0.518
	Total	108	100%	2	100%	110	
HBV vaccine	Yes	17	15.7%	0	0	17	
	No	91	84.3%	2	100%	93	0.520
	Total	108	100%	2	100%	110	
Duration of dialysis	Less than one year	9	8.3%	0	0	9	
	1- 10 year	49	45.4%	2	100%	51	
	More than 10	1	.9%	0	0	1	
	No	49	45.4%	0	0	49	0.502
	Total	108	100%	2	100%	110	
Jaundice	No	104	96.3%	2	100%	106	
	Yes	4	3.7%	0	0	4	0.846
	Total	108	100%	2	100%	110	
Needle injury	No	106	98%	2	100%	108	
	Yes	2	1.9%	0	0	2	0.782
	Total	108	100%	2	100%	110	

Variables	Туре	Mean	Std. Deviation	P value
Gender	Case	1.4	0.5	0.212
	Control	1.5	0.5	
Age	Case	2.2	0.8	0.626
	Control	2.3	0.9	
HBV vaccine	Case	1.7	0.5	0.000
	Control	2.0	0.0	
HBV infection	Case	1.5	0.5	0.000
	Control	1.0	0.0	
HCV infection	Case	1.0	0.2	0.196
	Control	1.0	0.0	

 Table 4: Correlation between Case and Control and the Study-Variables

## DISCUSSION

The result from our study demonstrated that the prevalence of HBV infection among the studied population was 26.3%, this result was less than the rates reported from different studies in Sudan, in which the rate of exposure to the HB virus ranged from 47% to%78, and varies from 6.8% in central Sudan to 26% in Southern Sudan (Hatim MY Mudawi, 2008) [22], and in many countries of Northern Africa, Asia, and South America, up to 70% (Jolanta Malyszko et al., 2018) [23]. In this study, the overall prevalence of anti-HCV was (1.8%) less than 40% has been reported from, Syria, Iran, Tunis, and Senegal (Bassam Bernieh, 2015) [24], and less than (17.3%) in Sudan (Karima Chaabna et al., 2016) [25]. In our study, there was a high prevalence of HBV infection among HD (45%) which was high compared with another study carried out in Sudan in 2016, in which the prevalence of HBV among HD (5%) and for HCV 6% C Hammad et al., (2016) in Sudan, and the incidence of HBV was higher in males(68.9%) than in female(31.1%)in another study the prevalence of hepatitis B surface antigen was slightly higher in males (54.6%) Emad Aldin, et al., (2012) in Khartoum [26, 27]. In our study, the prevalence of HBV increased with age, as it gradually increased after the age of 60 years (37.9%), in contrast to the prevalence in age groups less than 30 years In another study in India carried out by (Rubin Malhotra et al., 2016) the majority of patients were found to be 41-60 years of age (41.3%) followed by 21-40 years (31.5%). And then at 61-80 years (23.9%) [28]. In our study 27.5% (8/17) of vaccinated individuals had a positive result for HBV, this result differed from the result found by Hammed et al., (2016) none of the vaccinated patients were considered HBs Ag positive [29].

## **CONCLUSION**

In this study the prevalence of HBV among HD patients was very high (45%), therefor HD risk for HBV infection, these results emphasize the need to carry out proactive tasks for early diagnosis by using highly sensitive and specific methods such as real-time PCR technique, treatment of infected individuals and to vaccinate those with non-protective anti-HBs antibodies to reduce morbidity and mortality in HD patients.

#### Limitation

The study population was selected from one hospital, so the need for studying more population from different hospitals are recommended.

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There was no specific grant for this research from any funding organization in the public, private, or nonprofit sectors.

#### **Conflict of Interest**

The author has affirmed that there are no conflicting interests.

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