BMC Nephrology

RESEARCH

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Hepatitis B vaccination status among patients with end-stage kidney disease on haemodialysis in Ethiopia: a multi-center cross-sectional study

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Abstract

Background Chronic kidney disease patients, especially those on hemodialysis, are at increased risk of developing hepatitis B virus (HBV) infection. Guidelines suggest that all patients with chronic kidney disease patients should be vaccinated against HBV, but these guidelines are sub-optimally implemented. Notably, there is a lack of studies in Ethiopia examining the hepatitis B vaccination status among patients with end-stage renal disease.

Objective To assess the vaccination status of hepatitis B and associated factors among people with end-stage renal disease who were on hemodialysis.

Methods A multi-center cross-sectional observational study was conducted in six randomly selected dialysis centers in Ethiopia, from May 2023 to September 2023. Logistic regression analysis was used to evaluate factors associated with vaccination status. A person is considered to be vaccinated against hepatitis B if he/ she has taken at least one dose of HBV. Vaccination status was determined by patient's recall and verification from medical record.

Results Only 16% of patients with end-stage renal disease on hemodialysis were vaccinated against hepatitis B virus (16.6%; with CI = 12.18, 21.83), of which 30% had received one dose, 57.5% had two doses, 12.5% had three doses, and only five had a booster dose. Post-secondary education (AOR = 5.47; 95% CI = 1.41, 21.2; $P < 0.014$) and dialysis for more than three years (AOR = 19.75; 95% CI = 4.06, 96.1; $P < 0.001$) were significant factors associated with having received hepatitis B vaccination.

Conclusion Only a small minority of Ethiopian hemodialysis patients have received hepatitis B vaccination. The level of education of patients and the duration of time on dialysis were significant associated factors that affected the vaccination status of patients with end-stage renal disease. So, strong intervention is needed according to the identified factors to raise the vaccination status of patients.

Keywords Hepatitis B virus, Vaccination status, End-stage renal disease, Ethiopia

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Background

Infection with hepatitis B virus (HBV) remains an important global public health problem with significant morbidity and mortality [1]. WHO estimates that 296 million people were living with chronic hepatitis B infection in 2019, with 1.5 million new infections each year. In Ethiopia, the overall pooled prevalence of HBV was 6%. In 2019, hepatitis B resulted in an estimated 820,000 deaths, mostly from cirrhosis and hepatocellular carcinoma [2]. Despite the availability of effective vaccines since 1982, HBV infection has remained endemic in many countries [3].

Patients with end-stage kidney disease (ESKD) are at increased risk of acquiring HBV infection compared to the general population due to their deficient immune response, and the nature of hemodialysis procedures [4]. Specifically, patients receiving hemodialysis are considered at high risk of acquiring HBV infection [4]. Some of the factors associated with HBV propagation among hemodialysis patients include duration and frequency of hemodialysis, equipment contamination, and contact with other patients as well as healthcare workers [5, 6].

Guidelines from nephrology societies**,** Kidney Disease Improving Global Outcomes, and Centers for Disease Control and Prevention suggest that all patients with CKD should be vaccinated against HBV [7–9].

Among chronic kidney disease (CKD) populations, immune responses to HBV vaccination are impaired, proportionally to the degree of kidney failure. Hence, CKD patients experience lower seroconversion rates, lower peak antibody titers, and shorter durations of sero-protection [10]. Protective antibody titer is maintained only in 50% of CKD patients compared with 85% of healthy individuals after 1 year of vaccination. Strategies to improve response rates among CKD patients have included vaccination as early as possible in the course of renal disease, the use of double vaccine doses, and a four-dose rather than three-dose schedule. It is advised that these patients should be vaccinated at an earlier stage and before the start of hemodialysis because the response is better with higher eGFR [10, 11].

In Africa, the overall pooled prevalence of HBV among hemodialysis patients approaches 10% [12]. The prevalence of HBV and HCV infections in hemodialysis centers in Addis Ababa, Ethiopia was reported to be low [13]. HBV and HCV infections are among the important causes of infection-related morbidity and mortality in hemodialysis patients. Although acute infection tends to be mild and asymptomatic in dialysis patients, up to two-thirds may progress to chronic carriage, with a significant risk of chronic liver disease, premature death from cirrhosis or liver cancer, and nosocomial transmission within hemodialysis units [10]. In addition, viral hepatitis is the one of causes of morbidity and mortality resulting in a complication of hemodialysis treatment following cardiovascular disease and bacterial infection [12].

In developed countries, there has been a substantial decrease in the incidence of hepatitis B virus (HBV) infection in hemodialysis patients, probably attributable to screening of blood donors, a decline in blood transfusion requirements with increased erythropoietin use, identification of HBV-positive patients, use of dedicated dialysis machines, improved disinfection procedures, regular surveillance for HBV infection and active HBV vaccination before entering into dialysis program [14]. Despite this,risk of HBV infection is still present among patients undergoing dialysis and that HBV may be easily transmitted in the dialysis setting whenever appropriate infection control practices are not strictly applied [15].

Despite this, hemodialysis patients remain at increased risk of acquiring HBV because of prolonged vascular access, repeated exposure to blood products, shared hemodialysis equipment, immune-deficient state, and continuing high prevalence rates of HBV infection among hemodialysis populations. Blood product transfusions are vital components of the care of patients on hemodialysis, and The risk of hepatitis B virus (HBV) transmission through transfusion has significantly decreased over the last few decades due to careful donor selection and sensitive screening techniques. Common safety measures include testing blood donations for HBV antigens (HBsAg), hepatitis B core antibodies (anti-HBc), and HBV nucleic acid (NAT). However, despite these efforts, achieving zero residual risk remains challenging. Some studies suggest transfusion-related HBV infection may still be a concern in low-income countries due to the pre-seroconversion window period (WP), infection with immunovariant viruses, and occult carriage of HBV infection (OBI) [14].

Infections acquired in dialysis units can prolong hospitalization, increase treatment costs, and contribute to increased morbidity and mortality among CKD patients on dialysis. Dialysis patients with no prior exposure to HBV are at risk for acquiring HBV in the dialysis unit and should be vaccinated. Vaccination prevents patients on hemodialysis from acquiring HBV and reduces the pool of HBV-infected patients on dialysis. HBV vaccine has a significant protective effect against acquiring HBV infection in chronic hemodialysis patients. Despite this, there is a gap in vaccinating CKD patients against HBV.

WHO and the Ethiopian Federal Ministry of Health (FMOH) both encourage all high-risk individuals to be vaccinated against HBV Unfortunately, a non-mandatory strategy is being used for vaccination against HBV in high-risk individuals in the country. This research aimed to identify the HBV vaccination status of CKD patients

on maintenance hemodialysis, and factors associated with vaccination status within Ethiopia.

Material and methods

Study setting, design, and period

The study was conducted in Addis Ababa, the capital city of Ethiopia, and one of the largest urban centers in Sub-Saharan Africa. It has a total population of over 5 million persons and a population density of approximately 5,165 individuals per square kilometer [16]. The majority of the dialysis centers in Ethiopia are concentrated in the capital city of Addis Ababa, where 23 of the 35 units (66%) and 77% of the patients receiving dialysis are located [17]. In this study, six randomly selected dialysis centers (Private & Government) are included using the cluster sampling method The number of patients in dialysis centers varies widely, ranging from 10 to 250, with a median of 22. According to a 2021 survey, a total of 1132 patients were on hemodialysis in Ethiopia, making the prevalence about ten per million population [17].

Study period and design

Study period- This study was conducted between May 2023 and September 2023.

Stud design- Institution-based multi-center cross-sectional study design was employed.

Population

The source population was all CKD patients on maintenance hemodialysis at participating centers. The study population was all selected patients with CKD who were on maintenance hemodialysis during the study period. Patients reporting to the nephrology outpatient department (OPD), admitted in nephrology ward or reporting to dialysis unit with the diagnosis of CKD and on maintenance hemodialysis, age > 18 years, were included in the study. The patients tested positive for Hepatitis B surface antigen and CKD patients not on hemodialysis were excluded. Patients were included consecutively after obtaining informed consent from the patient.

Sample size and sampling technique

Sample size determination

For the first objective, the sample size was determined using a single population proportion formula at a 95% confidence interval with expected vaccination status against HBV of CKD patients on hemodialysis of 19% [18] with 5% precision and 10% added for possible non-response rate. The final sample size was $n = 259$.

The sample size for the second objective was calculated using Epi Info version 7.2.6.0. Socioeconomic class was the only factor associated with vaccination status in previous studies. The numbers of outcomes among the exposed and unexposed were 66.7% and 14.4% respectively. By assuming a 95% confidence interval, 80% power, and exposure to the unexposed ratio of 1:1, the calculated sample size was 34.

The final chosen sample size was 259 participants, accommodating both objectives. Consecutive sampling was used as a sampling technique. All people who met the inclusion criteria and were available were included in the study. Cluster random sampling was used as a sampling method among dialysis centers.

Data collection tools and procedure

Data were collected using a pretested interviewer-administered structured questionnaire. The questionnaire, which is attached as a supplemental file, asks about socio-demographic factors, clinical factors, and behavioral factors.

Study variables

Vaccination status was the outcome variable. Socio-demographic factors and clinical factors including duration of dialysis, comorbidity, and prospect/plan for renal transplantation were the independent variables.

Operational definitions

End-stage kidney disease (ESKD): is defined as an irreversible decline in a person's kidney function, which is severe enough to be fatal in the absence of dialysis or transplantation [19].

Vaccination status: a person is considered to be vaccinated against hepatitis B if he/ she has taken at least one dose of HBV.

Comorbidity: a person was considered to have comorbidity if they had at least one chronic medical disease in addition to ESKD [20].

Data collection and management

A structured interviewer-administered questionnaire was prepared after reviewing relevant literature. Data were collected by two health professionals with one supervisor. Data collectors obtained all relevant data related to socio-demographic, and clinical factors by interviewing the patients and additional information by reviewing patient medical records. The data collection tool was first prepared in English language and translated into Amharic language and then back to English. A 5% pretest was performed. Two days of training were provided to data collectors. Supervision was performed at each step of data collection and the collected data were checked for consistency and completeness before data analysis.

Data processing and analysis

The data were collected by using Kobo collect, and exported to Stata SE 18 (STATA Corporation. IC., TX, USA) [16] for data cleaning and statistical analysis. Descriptive analysis was used to describe the study findings. Both bi-variable and multivariable binary logistic regression models were fitted to identify the predictors of hepatitis B vaccination status among patients with ESKD. Independent variables having a *P*-value ≤ 0.25 in the bi-variable analysis were fitted into the final multivariable model for further analysis. Multi-collinearity between variables was checked using variance inflation factor (VIF) with a cut-off point with a median VIF < 5. The goodness of model fitness was checked by using the Hosmer and Lemeshow goodness of fit with $p \geq 0.05$ as a cutoff point. Adjusted Odd Ratio (AOR) with 95% confidence intervals (CI) and *P*-value ≤ 0.05 were used to assess the strength of association and statistical significance.

Result

Socio-demographic characteristics

A total of 259 participants were interviewed and 247 were included in the analysis,with response rate of 95%. The mean age of the respondents was 45.69 with a standard deviation of (± 14.96) years. The majority of the respondents (85.83%) were urban dwellers and 63.97% were males. Educational attainment varied, with 43.32% of participants having completed college or above the level of education. (Table 1).

Table 1 Socio-demographic characteristics of hemodialysis patients participating in this study (*n* = 247)

Variable	Categories	Frequency	Percentage
Age	18–24	16	6.48
	25–34	44	17.81
	35–44	59	23.89
	45–54	50	20.24
	55–64	47	19.03
	≥ 65	31	12.55
Sex	Male	158	63.97
	Female	89	36.03
Residence	Urban	212	85.83
	Rural	35	14.17
Marital Status	Married	152	61.79
	Single	66	26.83
	Widowed/Divorced	28	11.38
Level of Education	Primary	61	24.70
	Secondary	79	31.98
	College and above	107	43.32
Occupation	Civil servant	44	17.81
	Private worker	68	27.53
	Retired	37	14.98
	Unemployed	77	31.17
	Other (student, driver, housewife)	21	8.50

Clinical and laboratory-related factors

Among the study participants, 42.11% were on dialysis for more than three years. Only 41 (16.60%) of the study participants were vaccinated against HBV, of which 30% had received one dose, 57.5% had two doses, 12.5% had three doses, and only five had a booster dose. Reasons for not getting vaccinated included a lack of information (53.40%), safety concerns (5.83%), and issues related to access, affordability, and belief. About one-third of the patients had plans for kidney transplantation (31.58%). Comorbidities were prevalent in 92.71% of patients, commonly diabetes (23%) and hypertension (70%) (Table 2).

Factors associated with HBV vaccination

Bi-variable and multivariable logistic regression analysis

Table 3 shows the results of bi-variable logistic regression analysis. Factors that had an association at *p*-value ≤ 0.25 in bi-variable logistic regression were included in multivariable regression to control the effect of confounders. The level of education of the patients and duration of time on dialysis were found to be significant factors for the vaccination status of the hepatitis B virus among study participants.

End-stage kidney disease patients with college and above level of education were five times more likely to be vaccinated against hepatitis B than those who were at primary level of education (AOR = 5.47; 95% CI = 1.410988, 21.21483; *P* < 0.014). End-stage renal disease patients who were on dialysis for more than three years were five times more likely to be vaccinated against hepatitis B than those who were in dialysis for less than one year (AOR = 19.75; 95% CI = 4.061825, 96.11886; *P* < 0.001) (Table 3).

Discussion

The main goal of this study was to assess hepatitis B vaccination status and associated factors among end-stage kidney disease (ESKD) patients who were receiving hemodialysis in Ethiopia. The overall vaccination status among study participants was 16.6%, with half of the vaccinated patients having received only one or two vaccination doses. The patient's level of education and duration of time on dialysis were identified as significant factors associated with vaccination.

The Advisory Committee on Immunization Practices (ACIP) recommends hepatitis B vaccination for

Table 2 Clinical and laboratory characteristics of haemodialysis patients participating in this study ($n = 247$)

Variable	Categories	Frequency	Percentage
Duration on dialysis	< 1 year	60	24.29
	1–3 year	83	33.60
	> 3 year	104	42.11
Know HBV status	Yes	190	76.92
	No	57	23.08
Vaccinated against HBV	Yes	41	16.60
	No	206	83.40
Dose of HB Vaccine a	One	13	31.7
	Two	5	12.1
	Three	23	56
Booster dose	Yes	5	12.82
	No	34	87.18
Reason for not vaccinated	Lack of information on its importance	110	53.40
	Safety concerns about the vaccine	12	5.83
	Personal beliefs about vaccine	5	2.43
	Lack of access/availability of the vaccine	49	23.79
	Affordability/lack of money	14	6.80
	Lack of belief in the benefits of the vaccine	7	3.40
	Other	9	4.37
Plan for kidney transplantation	Yes	78	31.58
	No	169	68.42
Comorbidity	Yes	229	92.71
	No	18	7.29
Types of comorbidity	DM	72	23
	Hypertension	219	70
	Chronic liver disease	0	0
	HIV	9	2.9
	Heart Failure	13	4.1
Desire to be vaccinated in the future	Yes	172	83.90
	No	33	16.10

all dialysis patients and potential kidney transplant recipients [21, 22], and the low vaccination status of study participants is a finding requiring immediate intervention. Our finding is similar to a study from Pakistan [18]. However, vaccination status is lower than the studies done in England, Italy, France, and the USA [23–25]. This may be due to differences in socioeconomic factors. Developed countries often have better healthcare infrastructure, higher levels of health-related awareness, and greater economic resources, all of which contribute to higher vaccination rates. Additionally, individuals in these countries may be more likely to afford the cost of vaccinations, and healthcare systems are generally better equipped to implement and follow the recommended guidelines. On the contrary, less developed countries might face challenges related to healthcare accessibility, awareness, and economic limitations, leading to lower vaccination rates.

In the study, the level of education of the patients was found to be a significant determinant factor for hepatitis B vaccination status. Patients with ESKD who have a college education or better were more likely to be vaccinated against hepatitis B compared to those with a primary level of education. This is similar to the findings of a study of Ethiopian healthcare professionals [26, 27] and a Chinese study of men who have sex with men [28]. Higher educational attainment may be associated with better health literacy, greater access to information, proactive health advocacy, and potentially higher socioeconomic status, all of which contribute to an increased likelihood of vaccination among individuals with ESKD. Additionally, higher education levels may lead to a more informed and positive attitude towards vaccination, facilitating adherence to recommended practices.

Similarly, the duration of time on dialysis was identified as a significant factor influencing the hepatitis

Table 3 Bi-variable and Multivariable logistic regression analysis for factors associated with hepatitis B virus vaccination among hemodialysis patients participating in this study ($n = 247$)

Variables	Crude odd ratio (COR) with 95% CI	*P*-value	Adjusted odd ratio (AOR) with 95% CI	*P*-value
Age				
18–24	1		1	
25–34	0.71 (0.06, 8.45)	0.790	0.18 (0.00, 3.68)	0.266
35–44	3.43(0.40, 28.85)	0.255	0.88 (0.06, 12.53)	0.929
45–54	4.23 (0.50, 35.67)	0.185*	2.30 (0.14, 35.95)	0.550
55–64	4.58 (0.54, 38.71)	0.162*	2.18 (0.12, 37.05)	0.587
≥ 65	2.88 (0.30, 27.07)	0.354	1.01 (0.05, 20.05)	0.991
Gender				
Male	1		1	
Female	0.51 (0.24, 1.11)	0.093*	0.94 (0.34, 2.59)	0.919
Marital Status				
Married	1		1	
Single	0.56 (0.24, 1.29)	0.177*	1.03 (0.34, 3.13)	0.947
Divorced and Widowed	0.48 (0.13, 1.72)	0.265	0.25 (0.05, 1.18)	0.082
Level of Education				
Primary	1		1	
Secondary	2.80 (0.86, 9.09)	0.085*	3.55 (0.93, 13.56)	0.063
College and above	4.12 (1.35, 12.51)	0.012*	5.47 (1.41, 21.21)	0.014**
Occupation				
Civil Servant	1		1	
Private	0.36 (0.14, 0.93)	0.035*	0.46 (0.14, 1.53)	0.208
Retired	0.59 (0.21, 1.61)	0.306	0.62 (0.15, 2.53)	0.509
Unemployed	0.18 (0.06, 0.51)	0.001*	0.30 (0.08, 1.17)	0.085
other	0.35 (0.09, 1.41)	0.143*	0.99 (0.14, 6.60)	0.992
Duration of time on dialysis				
< 1 year	1		1	
1–3 years	2.67 (0.53, 13.33)	0.231*	3.65 (0.67, 19.69)	0.132
> 3 years	12.88 (2.96, 56.04)	0.001*	19.75 (4.06, 96.11)	< 0.001**
Plan for kidney transplantation				
Yes	1			
No	1.79 (0.80, 3.96)	0.150*	1.27 (0.47, 3.42	0.624

1 = reference, * statistically significant at *P*-value ≤ 0.25, ** statistically significant at *P*-value ≤ 0.05

B vaccination status of patients with end-stage kidney disease (ESKD). Individuals who had been on dialysis for more than three years were found to be more likely to be vaccinated against hepatitis B compared to those who had been on dialysis for less than one year. This may be due to the development of an increased awareness of vaccination importance due to prolonged healthcare interactions. Extended engagement with the healthcare system offers frequent opportunities for vaccination discussions and interventions. Longer dialysis duration heightens risk perception, motivating individuals to prioritize hepatitis B vaccination. The Kidney Disease Improving Global Outcomes (KDIGO) clinical management guideline recommends the administration of HBV vaccination as early as possible in the course of CKD as it has been associated with higher seroconversion rates. Since individuals with chronic kidney disease (CKD), particularly those on dialysis are at an increased risk of HBV infection, timely vaccination is essential to provide them with optimal protection against this serious viral infection. Early intervention not only enhances individual immunity but also contributes to public health efforts in preventing the spread of hepatitis B in the broader population, especially in healthcare settings where the risk of exposure may be higher. Therefore, the recommendation for early HBV vaccination in the context of chronic kidney disease aligns with efforts to maximize immunization

efficacy and safeguard the health of vulnerable individuals [29, 30].

Strength and limitation of the study

Strength of the study

The study includes more than 25% of patients and health facilities that give dialysis in Ethiopia, improving generalization.

Limitations of the study

Causation cannot be proven as a cross-sectional study was used. Participants relied on their memory to report past vaccination experiences. This may introduce recall bias. Due to the nature of the study HBV surface antibody determination was not done.

Conclusion and recommendations

Conclusion

The overall vaccination status among patients with end-stage kidney disease (ESKD) was low, and even among vaccinated individuals, the full vaccination course had usually not been administered. The level of education of patients and the duration of time on dialysis were significant associated factors for hepatitis virus vaccination. Intervention is needed to raise the HBV vaccination status of Ethiopian patients with ESKD.

Recommendations

For the Ethiopian ministry of health and Addis Ababa city administration health bureau

Advocacy for the development of a clear national HBV vaccination strategy and policy for high-risk individuals is crucial. Implementing effective, large-scale immunization strategies and interventions is essential to increase vaccination coverage and ensure health equity. Developing and implementing standard guidelines for the vaccination of patients with ESKD against the hepatitis B virus, as there is no standard guideline related to hepatitis B vaccination among patients with ESKD in Ethiopia, is recommended. Improving access to vaccines at affordable prices is important.

For health facilities and Healthcare providers

Patients with ESKD should be educated about the benefits of hepatitis B vaccination, and guidelines should be implemented.

For Researchers

Future studies should expand sample sizes and conduct Hepatitis B surface antibody (anti-HBs) titer to assess vaccine effectiveness in this population.

Abbreviations

CDC	Center for Disease Control
CKD	Chronic kidney disease
CLD	Chronic liver disease
ESKD	End-stage kidney disease
GFR	Glomerular filtration rate
HBV	Hepatitis B virus
KIDGO	Kidney Disease Improving Global Outcome
HIV	Human Immunodeficiency Virus

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12882-024-03703-x.

Supplementary Material 1.

Acknowledgements

We would like to thank Addis Ababa University, Sister Konjeet Metaferia Foundation (SKMF), Ethiopian Gastroenterology Association, Dialysis Centers, and the study participants for their great cooperation in this research.

Authors' contributions

R.T. developed the proposal, supervised data collection, did the analysis and interpretation of the result, and prepared the manuscript. A.M. worked on conception of the work, assisted in the design of the work, analysis, and interpretation of data, and Revised subsequent drafts of the paper. A.G. supervised and worked on data collection. A.Z. and L.H. supervised data collection and substantively revised the final manuscript. All authors read and approved the final manuscript.

Funding

Funding was obtained from Sister Konjeet Metaferia Foundation (SKMF) and the Ethiopian Gastroenterology Association during the conduct of this research. The funders had no role during data collection, analysis, or manuscript writing.

Availability of data and materials

The datasets used during the current study are available from the corresponding author upon reasonable request.

Declarations

Ethical approval and consent to participate

Before the study was conducted, an ethical clearance letter was obtained from the institutional review board (IRB) of Addis Ababa University with reference number IRB protocol number 100/223. Informed consent was obtained from each respondent. The purpose, potential risks and benefits of participating, and the right to withdraw from the study at any time were explained to the study participants. The information collected for this research was kept confidential and stored in files.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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Received: 3 March 2024 Accepted: 8 August 2024
Published online: 03 September 2024

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