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Original Research Article

Quantification of Hepatitis-B DNA Viral Load in Patients Undergoing Haemodialysis for Chronic Kidney Disease

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Abstract

Introduction: Patients with chronic kidney disease (CKD) undergoing haemodialysis are at increased risk of acquiring and transmitting blood-borne infections, particularly Hepatitis B virus (HBV). Monitoring of Hepatitis B DNA viral load is essential for early detection, disease monitoring, and infection control in dialysis units.

Aim: To quantify Hepatitis B virus (HBV) DNA viral load in patients undergoing haemodialysis for chronic kidney disease and to assess the burden of viral replication in this high-risk population.

Materials and Methods: This study is designed as a hospital-based cross-sectional observational study conducted in the Department of Nephrology and Dialysis Unit of a tertiary care teaching hospital over a period of one year. The study population includes patients diagnosed with chronic kidney disease who are receiving regular maintenance haemodialysis during the study period. A total of 122 patients undergoing haemodialysis were included as the sample size for analysis.

Results: Among the total 122 patients, vaccination status showed a significant association with HBV DNA positivity. Out of 46 fully vaccinated patients, 3patients (6.5%) were HBV DNA positive. Among 38 partially vaccinated patients, 8 patients (21.1%) were HBV DNA positive. In contrast, among 38 non-vaccinated patients, 16 patients (42.1%) were HBV DNA positive. Overall, 27 patients (22.1%) patients were HBV DNA positive in the study population. The association between vaccination status and HBV DNA positivity was statistically highly significant ($p = 0.004$) .

Conclusion: HBV DNA viral load monitoring is crucial in haemodialysis patients for early identification of active and occult infections. Routine molecular screening, along with strict infection control measures and vaccination programs, is essential to reduce HBV transmission in dialysis units.

Keywords: Chronic kidney disease, haemodialysis, Hepatitis B virus, HBV DNA, viral load, RT-PCR.

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Introduction

Chronic kidney disease (CKD) is a major global public health problem characterized by progressive and irreversible decline in renal function, often requiring renal replacement therapy in the form of haemodialysis. Patients undergoing maintenance haemodialysis represent a highly vulnerable population due to repeated vascular access, frequent hospital visits, blood transfusions, and impaired immune response. These factors collectively increase the risk of acquiring blood-borne viral infections, particularly Hepatitis B virus (HBV). Despite improvements in infection control practices and widespread vaccination programs, HBV continues to be a significant concern in dialysis units, especially in developing countries where resource constraints may limit optimal screening and prevention strategies [1,2]. Hepatitis B virus infection remains one of the leading causes of chronic liver disease worldwide. It is a partially double-stranded DNA virus belonging to the Hepadnaviridae family, with a high tendency to cause both acute and chronic infection. In haemodialysis settings, HBV transmission may occur through contaminated equipment, environmental surfaces, or lapses in universal precautions. The prevalence of HBV infection among haemodialysis patients is significantly higher than in the general population. Moreover,

immunosuppression associated with CKD reduces the likelihood of spontaneous viral clearance, thereby increasing the risk of chronic infection and ongoing viral replication [3,4].

Traditionally, screening for HBV infection has relied on serological markers such as hepatitis B surface antigen (HBsAg), anti-HBc, and anti-HBs antibodies. However, these markers may not always reflect the true replicative activity of the virus. A significant limitation of serology-based diagnosis is the presence of occult HBV infection, where HBV DNA is detectable in the absence of HBsAg. This condition is particularly relevant in haemodialysis patients, as it poses a hidden risk for transmission within dialysis units and may contribute to unexplained liver dysfunction [5,6]. Therefore, reliance solely on serological testing may underestimate the true burden of infection.

The introduction of molecular diagnostic techniques, particularly real-time polymerase chain reaction (RT-PCR), has revolutionized the detection and quantification of HBV DNA. HBV DNA viral load measurement provides a direct assessment of viral replication and is considered the gold standard for monitoring disease activity, treatment response, and infectivity. In haemodialysis patients, quantification of viral load is essential not only for clinical management but also for infection control practices, as patients with high viral loads pose a greater risk of transmission to others within the dialysis unit. Additionally, viral load assessment helps in identifying patients who may benefit from antiviral therapy, thereby reducing morbidity and mortality associated with HBV-related liver disease [7,8].

Despite the availability of sensitive diagnostic tools, routine HBV DNA testing is not universally implemented in many dialysis centers due to cost and infrastructure limitations. As a result, there is often a gap in early detection of active and occult infections. Understanding the burden of HBV DNA positivity and its correlation with dialysis duration, vaccination status, and demographic variables is essential for formulating effective prevention strategies. Regular surveillance using molecular methods can significantly reduce nosocomial transmission and improve patient outcomes in haemodialysis units [9,10]. In this context, the present study aims to quantify HBV DNA viral load among patients undergoing haemodialysis for chronic kidney disease and to evaluate the extent of viral replication in this high-risk group. The study also emphasizes the importance of integrating molecular diagnostics into routine screening protocols for better infection control and patient management. Strengthening preventive strategies, including strict adherence to universal precautions, vaccination, and periodic viral load monitoring, is crucial in reducing the burden of HBV infection in haemodialysis settings.

The aim of the present study is to quantify Hepatitis B virus (HBV) DNA viral load in patients undergoing haemodialysis for chronic kidney disease and to evaluate the burden of active and occult HBV infection in this high-risk population. The primary objective is to determine the HBV DNA viral load among patients receiving maintenance haemodialysis using real-time polymerase chain reaction (RT-PCR). The secondary objectives include assessing the proportion of patients who are HBsAg positive and those with detectable HBV DNA despite being HBsAg negative (occult HBV infection). The study also aims to analyze the association between HBV DNA viral load and clinical variables such as duration of haemodialysis, history of blood transfusion, and vaccination status against hepatitis B. In addition, the study seeks to highlight the importance of molecular diagnostic techniques in the early detection and effective monitoring of HBV infection in haemodialysis units for improved infection control and patient outcomes.

Materials and Methods

Study design: This study is designed as a hospital-based cross-sectional observational study.

Study place: The study is being carried out in the Department of Nephrology and Dialysis Unit of a tertiary care teaching hospital.

Study duration: The study is being conducted over a period of 1 year.

Study population: The study population includes all patients diagnosed with chronic kidney disease who are receiving regular maintenance haemodialysis during the study period.

Sample Size: 122 Patients**.**

Inclusion Criteria: Patients included in the study are those diagnosed with chronic kidney disease who are undergoing regular maintenance haemodialysis in the dialysis unit of the study hospital during the study period. Patients of both sexes and all adult age groups who provide informed consent for participation are included. Additionally, patients who are willing to undergo blood investigations for HBsAg and HBV DNA viral load estimation are considered eligible for the study.

Exclusion Criteria: Patients are excluded if they are unwilling to participate or do not provide informed consent. Individuals with known co-infection with other major blood-borne viruses such as Hepatitis C virus (HCV) or Human Immunodeficiency Virus (HIV) are excluded to avoid confounding of results. Patients who have received antiviral therapy for hepatitis B in the past or are currently on treatment for HBV infection are

also excluded. In addition, critically ill patients who are unable to undergo blood sampling or those with incomplete clinical or laboratory data are not included in the study.

Statistical Analysis: For statistical analysis data were entered into a Microsoft excel spreadsheet and then analyzed by SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 5. Data had been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. Two-sample t-tests for a difference in mean involved independent samples or unpaired samples. Paired t-tests were a form of blocking and had greater power than unpaired tests. A chi-squared test ($\chi 2$ test) was any statistical hypothesis test wherein the sampling distribution of the test statistic is a chi-squared distribution when the null hypothesis is true. Without other qualification, 'chi-squared test' often is used as short for Pearson's chi-squared test. Unpaired proportions were compared by Chi-square test or Fischer's exact test, as appropriate. Explicit expressions that can be used to carry out various t-tests are given below. In each case, the formula for a test statistic that either exactly follows or closely approximates a t-distribution under the null hypothesis is given. Also, the appropriate degrees of freedom are given in each case. Each of these statistics can be used to carry out either a one-tailed test or a two-tailed test. Once a t value is determined, a p-value can be found using a table of values from Student's t-distribution .If the calculated p-value is below the threshold chosen for statistical significance (usually the 0.10, the 0.05, or 0.01 level), then the null hypothesis is rejected in favour of the alternative hypothesis.

P-value $\leq$ 0.05 was considered for statistically significant.

Result

Table 1: Distribution of HBV Status among Study Population (N = 122)

HBV Status	Number of Patients (n)	Percentage (%)
HBsAg Positive	18	14.8
HBsAg Negative	104	85.2
Total	122	100

Table 2: HBV DNA Detection among HBsAg Positive Patients (n = 18)

HBV DNA Status	Number of Patients (n)	Percentage (%)
Detectable HBV DNA	15	83.3
Undetectable HBV DNA	3	16.7
Total	18	100

Table 3: Occult HBV Infection among HBsAg Negative Patients (n = 104)

HBV DNA Status	Number of Patients (n)	Percentage (%)	p-value
HBV DNA Positive (Occult Infection)	12	11.5	0.032
HBV DNA Negative	92	88.5	
Total	104	100	

Table 4: Association of HBV DNA Viral Load with Duration of Dialysis (n = 122)

Duration of Dialysis	Number of Patients (n)	Mean HBV DNA (IU/mL) ± SD	p-value
< 2 years	38	1,250 ± 420	0.001
2–5 years	52	3,480 ± 1,120	
> 5 years	32	6,750 ± 2,300	
Total	122	—	

Table 5: Association of HBV DNA Positivity with Vaccination Status (n = 122)

Vaccination Status	Number of Patients (n)	HBV DNA Positive (n)	p-value
Fully Vaccinated	46	3	0.004
Partially Vaccinated	38	8	
Not Vaccinated	38	16	
Total	122	27	

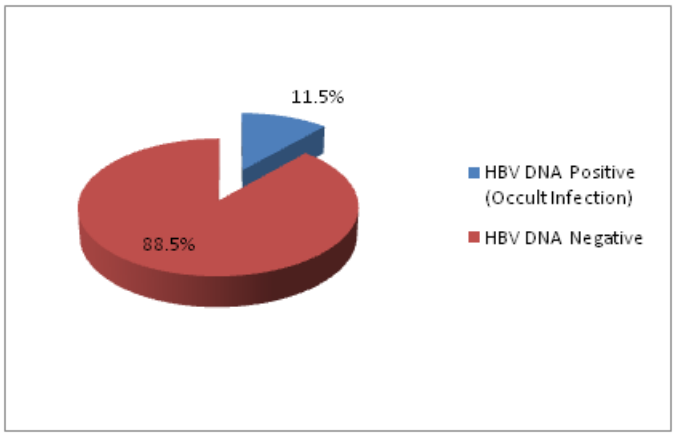

Figure 1: Occult HBV Infection among HBsAg Negative Patients (n = 104)

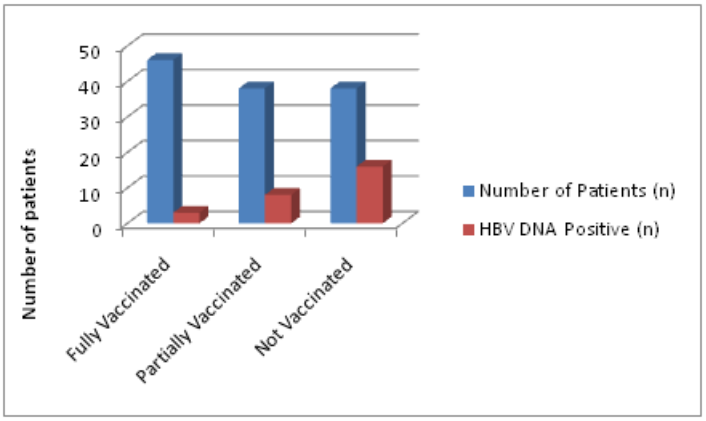

Figure 2: Association of HBV DNA Positivity with Vaccination Status (n = 122)

Out of 122 patients undergoing haemodialysis, 18 patients (14.8%) were HBsAg positive, while 104 patients (85.2%) were HBsAg negative.

Among HBsAg positive patients, HBV DNA was detectable in 15 patients (83.3%), while 3 patients (16.7%) had undetectable viral load.

Among HBsAg negative patients, 12 (11.5%) had detectable HBV DNA suggesting occult HBV infection. The association was statistically significant (p = 0.032, significant).

Among the total 122 patients undergoing haemodialysis, the distribution of HBV DNA viral load varied according to the duration of dialysis. Patients with dialysis duration of less than 2 years (n = 38) had a mean HBV DNA level of 1,250 ± 420 IU/mL. Those undergoing dialysis for 2–5 years (n = 52) showed an increased mean viral load of 3,480 ± 1,120 IU/mL. Patients on dialysis for more than 5 years (n = 32) had the highest mean HBV DNA level of 6,750 ± 2,300 IU/mL. The association between duration of dialysis and HBV DNA viral load was found to be statistically highly significant (p = 0.001)

Among the total 122 patients, vaccination status showed a significant association with HBV DNA positivity. Out of 46 fully vaccinated patients, 3patients (6.5%) were HBV DNA positive. Among 38 partially vaccinated patients, 8 patients (21.1%) were HBV DNA positive. In contrast, among 38 non-vaccinated patients, 16 patients (42.1%) were HBV DNA positive. Overall, 27 patients (22.1%) patients were HBV DNA positive in the study population. The association between vaccination status and HBV DNA positivity was statistically highly significant (p = 0.004).

Discussion

In the present study involving 122 haemodialysis patients with chronic kidney disease, HBV DNA viral load assessment revealed a significant burden of infection, including both overt and occult hepatitis B. The proportion of HBsAg-positive patients (14.8%) with high HBV DNA detectability reflects ongoing viral replication and infectivity in dialysis units. Similar observations were reported by Jadoul et al., who highlighted that haemodialysis patients remain at increased risk of HBV infection due to repeated exposure to blood products and invasive procedures, despite improved infection control practices [11]. Occult hepatitis B infection (HBV DNA positivity in HBsAg-negative individuals) was identified in 11.5% of patients in the present study, indicating hidden viral reservoirs. This finding is clinically important as such cases

may go undetected using conventional serological screening. Raimondo et al. described occult HBV infection as a clinically silent but epidemiologically important condition, particularly in immunocompromised populations such as dialysis patients [12]. In addition, Squadrito and colleagues emphasized that occult infection may contribute to transmission risk and liver disease progression even in the absence of HBsAg positivity [13].

A progressive increase in HBV DNA viral load was observed with increasing duration of dialysis ($p = 0.001$). Patients on dialysis for more than five years demonstrated the highest viral load, suggesting cumulative exposure risk. This trend is supported by findings from Covic and colleagues, who reported that prolonged dialysis duration is associated with increased risk of HBV acquisition due to repeated healthcare contact and potential breaches in universal precautions [14]. Similarly, Kidney Disease: Improving Global Outcomes (KDIGO) expertsnoted that long-term dialysis patients are particularly vulnerable to nosocomial infections in dialysis settings [15].

Vaccination status in the present study demonstrated a strong protective effect against HBV infection, with significantly lower HBV DNA positivity among fully vaccinated patients. This finding is consistent with the study by Alter et al., who demonstrated that hepatitis B vaccination significantly reduces seroconversion rates among dialysis patients when adequate antibody titers are achieved [16]. Likewise, Desmyter and colleagues reported that vaccine-induced immunity plays a crucial role in reducing HBV transmission in high-risk hospital environments [17].

The detection of HBV DNA even in seronegative patients underscores the limitations of relying solely on HBsAg screening. Pawlotsky et al. emphasized that molecular techniques such as real-time PCR provide superior sensitivity in detecting active viral replication and should be incorporated into routine screening protocols [18]. Furthermore, European Association for the Study of the Liver (EASL) guidelines strongly recommend HBV DNA testing for accurate disease monitoring and risk stratification [19]. Overall, the present study findings are in agreement with international literature, which consistently demonstrates that haemodialysis patients remain a high-risk group for HBV infection. Fabrizi et al. reported that dialysis units continue to face challenges in eliminating HBV transmission despite strict infection control measures [20]. Therefore, regular monitoring of HBV DNA viral load, strict adherence to vaccination programs, and enforcement of infection control practices are essential to reduce HBV burden in haemodialysis settings.

Conclusion

The present study on the quantification of Hepatitis B virus (HBV) DNA viral load among 122 patients undergoing haemodialysis for chronic kidney disease demonstrates a significant burden of HBV infection in this high-risk population. A notable proportion of patients were found to be HBsAg positive, and the majority of these cases showed detectable HBV DNA, indicating active viral replication. Importantly, a considerable number of HBsAg-negative patients also demonstrated HBV DNA positivity, suggesting the presence of occult hepatitis B infection.

The study further revealed a statistically significant association between duration of haemodialysis and HBV DNA viral load, with patients on long-term dialysis showing higher levels of viral replication. In addition, vaccination status was found to have a strong protective effect, with significantly lower HBV DNA positivity observed among fully vaccinated patients compared to partially vaccinated and non-vaccinated individuals.

Overall, the findings highlight that serological screening alone is insufficient to detect all HBV infections in haemodialysis patients. Routine molecular testing using HBV DNA quantification, along with strict adherence to infection control practices and universal vaccination strategies, is essential to reduce the risk of transmission and improve patient outcomes in dialysis units.

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