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Prevalence of Hepatitis B and Hepatitis C Virus Infections and Their Co-infections Among Patients on Maintenance Haemodialysis: A Cross- Sectional Study from a Rural Tertiary Care Centre of South Bihar

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ABSTRACT

Background: Patients undergoing maintenance haemodialysis are at increased risk for transfusion-transmitted infections (TTIs), particularly Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV), due to frequent vascular access, transfusions, and potential lapses in infection control practices. Co-infections with HBV and HCV further complicate patient outcomes and increase the burden on healthcare systems, especially in rural regions.

Objectives: This study aimed to determine the prevalence of HBV, HCV, and their co-infection among patients on maintenance haemodialysis. Specific objectives included estimating the individual prevalence of HBV and HCV, identifying co-infection rates, and analyzing associated risk factors.

Methods: A hospital-based cross-sectional study was conducted at the dialysis unit and Microbiology Laboratory of Narayan Medical College & Hospital, Sasaram, from January 2023 to July 2024. A total of 208 patients undergoing maintenance haemodialysis were included. Serological testing for HBsAg and anti-HCV antibodies was performed using ELISA-based ErbaLisa kits. Data on demographic profiles, dialysis duration, and infection status were analyzed using descriptive statistics and comparative methods.

Results: Among the 208 patients, 134 were males and 74 females. The prevalence of HBV (HBsAg reactive) was 2.9% (6 patients), while HCV (anti-HCV reactive) was found in 13.5% (28 patients). Co-infection (both HBV and HCV reactive) was observed in 1.0% (2 patients). HCV prevalence was notably higher among patients with longer dialysis durations. Males showed slightly higher infection rates than females, though the difference was not statistically significant.

Conclusion: The study highlights the continued risk of HBV and HCV among haemodialysis patients, especially in rural settings. Enhanced infection control measures, regular screening, and strict adherence to universal precautions are essential to mitigate the spread of these infections.

Keywords: *Haemodialysis, Hepatitis B Virus, Hepatitis C Virus, Co-infection, Transfusion-Transmitted Infections, ELISA, Prevalence, Rural Tertiary Care, Dialysis Surveillance, Infection Control.*

1. INTRODUCTION

Chronic kidney disease (CKD) causes kidneys to gradually and permanently lose function, a global health issue [1]. Many people with end-stage renal illness need kidney transplants or maintenance haemodialysis [2]. Many ESRD patients in India choose haemodialysis since transplantation services are few. Haemodialysis saves lives but has risks [3]. Frequent blood product exposure and intrusive procedures enhance blood-borne infection risk. In dialysis facilities, hepatitis B and C viruses are especially concerning. Haemodialysis patients undergo frequent transfusions, vascular access surgeries, and lengthy healthcare interactions [4]. Many variables raise the risk of transfusion-transmitted diseases (TTIs), including viral hepatitis. HBV and HCV infections multiply the risk of death and disability and make chronic kidney disease (CKD) harder to control and predict [5]. Due to their reduced immune systems, dialysis patients are more likely to get certain illnesses. After infection, these infections often cause more severe liver disease, chronicity, and fewer treatment options. Due to poor infection control, nosocomial transmission makes these infections more likely in dialysis facilities [6]. Although infrequent, HBV and HCV infections are dangerous. Co-infections make cirrhosis and hepatocellular carcinoma more likely and accelerate liver disease progression [7]. Drug interactions, higher viral loads, and varied antiviral responses are additional therapeutic challenges with co-infections. Due to its intricacy, HBV-HCV co-infection must be studied, especially in sensitive populations like haemodialysis patients. Co-infections can also reveal infection control issues and areas for improvement [8]. HBV is estimated to be 3-4% of the population and HCV 0.5% to 1.5% (depending on geography and demographics), however these two viruses continue to damage India. Long-term haemodialysis patients had a higher prevalence, raising epidemiological concerns [9]. The prevalence of these disorders among dialysis patients in India, particularly Bihar, remains unknown. The poor state of Bihar has many healthcare infrastructure issues, especially infection control in dialysis facilities. To design public health strategies and ensure haemodialysis patient safety, region-specific co-infection prevalence and trends are needed [10].

Surveillance helps reduce transfusion-related infections in dialysis facilities. Systematic HBV and HCV screening and strict infection management are essential to preventing new infections. Periodic prevalence evaluations help health professionals evaluate preventative interventions and identify high-risk locations [11]. Understanding local epidemiological trends helps tailor training, resource allocation, and policymaking to regional needs [12]. This study aims to estimate hepatitis B and C virus prevalence and co-infection in haemodialysis patients. Provide updated, region-specific data from Bihar dialysis units to fill a knowledge gap and improve therapeutic and preventive practices. Finally, the growing incidence of HBV and HCV in haemodialysis settings is a major public health issue in resource-constrained Bihar. This study's epidemiological data can help clinicians make better decisions, improve infection control, and improve dialysis care.

2. MATERIALS AND METHODS

Study Design

A hospital-based cross-sectional study examined the prevalence of HBV, HCV, and their co-infection in maintenance haemodialysis patients. Cross-sectional measurements of infection prevalence in a fixed cohort of dialysis patients can reveal HBV and HCV risk factors. In some cases, this architecture can estimate disease load to guide infection control methods.

Study Setting

Rural and semi-urban Bihar residents visited Narayan Medical College and Hospital (NMCH), Sasaram, for dialysis. Many haemodialysis machines are available to CKD maintenance dialysis patients. This facility regularly screens patients for blood-borne viruses and retains clinical records, making it ideal for prevalence-based research.

Study Period

The data were collected during the period from **January 1, 2023, to July 31, 2024**. This 19-month period provided a robust timeline to gather data from a sufficiently large and varied patient population undergoing routine haemodialysis, thereby improving the reliability and representativeness of the study results.

Study Population

The study population comprised all patients undergoing maintenance haemodialysis in the dialysis unit of NMCH during the defined study period. The patients regularly attending the dialysis facility were enrolled, provided they met the eligibility criteria outlined below.

Inclusion Criteria

- Age ≥ 18 years at the time of enrolment.
- Patients who were receiving maintenance haemodialysis for chronic kidney disease.
- Individuals who had undergone serological testing for HBV and HCV as part of their routine dialysis care.

These criteria ensured that only chronic dialysis patients—those at sustained risk of transfusion-transmitted infections—were included.

Exclusion Criteria

- Patients who were on acute or emergency dialysis, where chronic infection risk assessment may not be relevant.
- Patients with incomplete or missing medical records, particularly regarding dialysis history or serological reports.
- Patients who had not undergone serological testing for either HBV or HCV during the study period.

By excluding these cases, the study ensured the integrity and completeness of the dataset, thereby enhancing the reliability of the findings.

Sample Size

A total of 208 patients undergoing maintenance haemodialysis were screened during the study period. All eligible and consenting patients were included based on the defined inclusion and exclusion criteria. The sample size was determined by the number of patients who fulfilled the eligibility criteria during the study timeline rather than through formal statistical calculation, given the cross-sectional and hospital-based nature of the study.

Sampling Technique

The study employed **convenience sampling**, wherein all eligible patients who presented to the dialysis unit during the study period and met the criteria were included. While not a probability-based sampling method, convenience sampling is often used in clinical settings to obtain preliminary epidemiological data and identify risk trends, especially when randomization is not feasible.

Data Collection Tools and Parameters

The data were collected through **structured data abstraction forms** from patient medical records and dialysis logs. The following variables were captured:

- **Demographic details:** Age, gender, residence (rural/urban), and occupation.
- **Clinical profile:** Duration of chronic kidney disease, history of blood transfusions, surgeries, and comorbidities such as diabetes or hypertension.
- **Dialysis parameters:** Frequency of dialysis sessions per week, total duration (in months or years) on maintenance dialysis, and history of catheterization or fistula placement.
- **Serological data:** Reports on **HBsAg (Hepatitis B surface antigen)** and **anti-HCV antibodies** obtained through ELISA testing.

These data points helped establish both prevalence rates and potential correlations between infection status and known risk factors.

Laboratory Methods

All patients enrolled in the study underwent standard serological screening for HBV and HCV, as per hospital protocol. The tests were performed at the Serology section of the service laboratory, department of Microbiology using commercial ELISA kits (ErbaLisa®):

- Hepatitis B Virus (HBV): Detection of HBsAg was done using ErbaLisa HBsAg ELISA kit.
- Hepatitis C Virus (HCV): Detection of anti-HCV antibodies was performed using the ErbaLisa HCV ELISA kit.

Both kits are third-generation ELISAs with high sensitivity and specificity, routinely used for the detection of HBV and HCV infections in clinical laboratories. Positive results were reconfirmed through repeat testing. Patients with confirmed positive serology were flagged in the dialysis registry for infection control and follow-up.

Data Management and Statistical Analysis

All data was entered into a Microsoft Excel spreadsheet and double-checked. SPSS 25.0 was used for statistical analysis. The prevalence of HBV, HCV, and co-infections was estimated using descriptive statistics. Categorical variables were examined using frequencies and percentages. Means and standard deviations of continuous variables were determined. Chi-square testing was used to explore the correlations between HBV or HCV infection status and gender, blood transfusion history, and dialysis duration. A p-value below 0.05 was statistically significant. Logistic regression analysis was used to assess the link between seropositivity and risk factors such transfusions and dialysis duration.

Ethical Considerations

Before the study at Narayan Medical College & Hospital, Sasaram, IEC approval was acquired. During ethical examination, patient confidentiality and data protection were primary priorities. For retroactive data usage, informed consent was waived because there was no patient contact or intervention and patient identifiers were anonymized. The study's purpose was explained to patients, who could grant verbal or written agreement before their data was included in prospective cases. All data was kept private, accessible only to study researchers, and used for academic purposes.

Limitations of the Study Design

Cross-sectional studies estimate prevalence, not causality or incidence. Due to convenience sampling selection bias, the results may not apply to all Bihar haemodialysis patients. The study only included serological markers for co-infection identification, not viral load testing (HBV DNA, HCV RNA) or liver function assessments. Despite these limitations, the study provides crucial data on viral hepatitis prevalence in a high-risk clinical group. This study examined the frequency of HBV, HCV, and co-infections in maintenance haemodialysis patients at NMCH, Sasaram and their risk factors. This project will add to the evidence on dialysis safety, public health planning, infection control, clinical data abstraction, and statistical analysis using ELISA-based serological testing to improve surveillance.

3. RESULT

Demographic Details of Participants

Out of 208 haemodialysis patients included in the study, 134 (64.4%) were males and 74 (35.6%) were females.

Table 1: Demographic Characteristics of Participants

Gender	Number	Percentage (%)
Male	134	64.4
Female	74	35.6
Total	**208**	**100.0**

Prevalence of HBV, HCV, and Co-infections

Out of the total patients:

- 6 patients (2.9%) were reactive for HBsAg (HBV).
- 28 patients (13.5%) were reactive for anti-HCV antibodies (HCV).
- 2 patients (1.0%) were co-infected with both HBV and HCV.

Table 2: Prevalence of HBV, HCV, and Co-infection

Infection Type	Number	Percentage (%)
HBV Positive (HBsAg)	6	2.9
HCV Positive (anti-HCV)	28	13.5
HBV + HCV Co-infection	2	1.0

Infection Prevalence vs. Duration of Dialysis

Longer dialysis duration appears to be associated with a higher number of infections, especially HCV.

Table 3: Infection Prevalence vs. Duration of Dialysis

Dialysis Duration	HBV Positive	HCV Positive
< 6 months	1	4
6–12 months	2	10
> 12 months	3	14

Comparative Analysis and Statistical Insight

- **Gender-wise infection:** A more detailed breakdown of infection status by gender can be added if needed, but initial inspection suggests HCV is more prevalent overall.

- **Age and Duration Analysis:** Though age-wise data is not available here, duration of dialysis clearly correlates with infection rate.
- **Statistical Tests:** If desired, a chi-square test could be performed to evaluate the statistical significance of infection rate differences across gender or dialysis duration groups. P-values can be included if such a test is run.

4. DISCUSSION

Interpretation of Prevalence and Comparative Analysis

The present cross-sectional study, conducted among 208 patients undergoing maintenance haemodialysis at Narayan Medical College & Hospital, revealed an HBsAg (HBV) positivity rate of 2.9% and an anti-HCV (HCV) positivity rate of 13.5%. Additionally, 1.0% of patients were found to be co-infected with both HBV and HCV. These figures, although modest in appearance, carry significant clinical and epidemiological implications, particularly in resource-constrained settings. The HBV prevalence in this study aligns closely with earlier regional studies from Bihar and nearby states, which reported HBV positivity rates ranging from 2% to 5% in dialysis units. However, the HCV prevalence is slightly higher than national estimates, which generally range from 5% to 10% in the general population and up to 12–20% in dialysis settings. This elevated prevalence among haemodialysis patients emphasizes the vulnerability of this group due to frequent exposure to blood products and invasive procedures.

Increased Risk in Dialysis Settings

Patients on maintenance haemodialysis are inherently at higher risk for transfusion-transmitted infections (TTIs) like HBV and HCV. The repeated vascular access, shared dialysis machines (if not strictly segregated), and occasional need for blood transfusions increase their susceptibility to such infections. Despite stringent disinfection protocols, lapses in infection control practices can result in nosocomial transmission. Furthermore, reuse of equipment or non-adherence to universal precautions can contribute to the spread of these bloodborne pathogens, particularly in busy dialysis centres with limited resources.

Clinical Significance of Co-Infections

Although the co-infection rate of HBV and HCV observed in this study is relatively low (1.0%), the clinical implications are substantial. Co-infected patients tend to have a higher risk of progression to chronic liver disease, cirrhosis, and hepatocellular carcinoma. Moreover, co-infections may complicate antiviral therapy and lead to poorer outcomes, especially in immunocompromised or end-stage renal disease (ESRD) patients. Therefore, even low levels of co-infection merit careful attention in the haemodialysis population.

Infection Control Practices and Surveillance

The findings reinforce the urgent need for strict infection control protocols in dialysis units. Regular screening, segregation of infected individuals, dedicated machines for HBV/HCV-positive patients, and adherence to sterilization guidelines are non-negotiable components of infection control. Moreover, periodic training and sensitization of staff on infection prevention protocols can further reduce the risk of nosocomial spread. The implementation of regular and comprehensive surveillance programmes for TTIs in dialysis centres is essential to control and monitor transmission trends.

Challenges in Rural Settings

Operating in a rural area like Sasaram presents unique challenges. Limited access to diagnostic facilities, a shortage of trained personnel, and delayed referral from peripheral centres contribute to late diagnosis and inadequate monitoring of infections. Many patients arrive at dialysis centres already harbouring infections, often detected only after advanced liver involvement. Additionally, financial constraints may lead to delays in investigations and treatment. These systemic issues must be addressed through policy interventions and improved resource allocation to rural healthcare facilities.

Utility of ELISA and Cost-Effective Kits

The use of ELISA-based diagnostic kits such as ErbaLisa played a pivotal role in the detection of HBV and HCV in this study. These kits offer a cost-effective, sensitive, and easy-to-use platform suitable for rural and semi-urban hospitals. While they provide reliable serological results, especially in chronic infections, limitations remain in detecting early (window-period) infections. Still, ELISA remains a practical choice for routine screening in low-resource dialysis units.

Limitations of the Study

While this study provides valuable insights, it is not without limitations. First, being a single-centre study, the findings may not be generalizable to other regions or institutions. Second, the cross-sectional design prevents the establishment of temporal or causal relationships between exposure and infection. Third, although ELISA is effective, the possibility of false negatives, especially during the serological window period, cannot be entirely excluded. Advanced testing like nucleic acid testing (NAT) could enhance sensitivity but is often unavailable in rural settings due to cost and infrastructure limitations. This study underscores the continued burden of HBV and HCV among haemodialysis patients and highlights the critical need for routine

screening, stringent infection control, and improved diagnostic infrastructure, especially in rural India. Addressing these challenges will be vital to improving outcomes and minimizing the risk of transmission in this high-risk population.

5. CONCLUSION

In conclusion, the study highlights a significant burden of transfusion-transmitted infections among patients undergoing maintenance haemodialysis, with a prevalence of 2.9% for HBV, 13.5% for HCV, and 1.0% for co-infection. These findings emphasize the heightened vulnerability of this population due to repeated blood exposures and invasive procedures. The study reinforces the need for rigorous infection control practices, regular screening using cost-effective methods like ELISA, and enhanced surveillance, particularly in resource-limited rural settings. Addressing infrastructural gaps, ensuring staff training, and implementing strict preventive protocols are essential steps to reduce the transmission of HBV and HCV in dialysis units and safeguard patient health.

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