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A STUDY OF HEPATITIS B POSITIVITY DETECTED BY MOLECULAR METHODS AND ITS CORRELATION WITH LABORATORY FINDINGS AMONG HEPATITIS B POSITIVE PATIENTS IN A SELECTED HOSPITAL OF UJJAIN, MADHYA PRADESH

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ABSTRACT

Background:

Hepatitis B virus (HBV) infection remains a significant global public health challenge due to its potential for chronic infection and severe hepatic complications. Molecular diagnostic methods such as polymerase chain reaction (PCR) offer high sensitivity and specificity for detecting HBV DNA and estimating viral load. Correlating HBV positivity with routine laboratory findings can enhance clinical interpretation and guide patient management.

Objective:

To determine the prevalence of hepatitis B positivity using molecular methods and assess its correlation with laboratory parameters among hepatitis B positive patients in a selected hospital of Ujjain, Madhya Pradesh.

Methods:

A cross-sectional descriptive study was conducted among 120 patients who tested positive for Hepatitis B surface antigen (HBsAg) at [Hospital Name], Ujjain. HBV DNA detection and quantification were performed by real-time PCR. Laboratory parameters including liver function tests (ALT, AST, ALP, total bilirubin), platelet count, and

prothrombin time were collected and analyzed. Statistical correlation between viral load and laboratory markers was assessed using Pearson's correlation coefficient; $p < 0.05$ was considered statistically significant.

Results:

Out of 120 HBsAg positive patients, 92 (76.7%) demonstrated detectable HBV DNA by molecular methods. Elevated ALT and AST levels were noted in patients with high viral load. Significant positive correlation was observed between HBV DNA levels and ALT ($r = 0.64$, $p < 0.001$) and AST ($r = 0.58$, $p < 0.001$). Platelet count showed an inverse correlation with HBV DNA levels ($r = -0.42$, $p = 0.002$). No significant correlation was detected between HBV DNA levels and total bilirubin or ALP.

Conclusion:

Molecular detection of HBV DNA demonstrated a high positivity rate among HBsAg positive patients. Significant correlations between viral load and key liver enzymes suggest that elevated liver enzymes reflect active viral replication. Integration of molecular diagnostics with routine laboratory findings enhances clinical assessment and decision-making in HBV management.

Keywords:

Hepatitis B, molecular methods, PCR, liver function tests, viral load, Ujjain, Madhya Pradesh

INTRODUCTION

Hepatitis B virus (HBV) infection is a major cause of liver disease worldwide and a significant contributor to chronic hepatitis, cirrhosis, and hepatocellular carcinoma. According to the World Health Organization, an estimated 296 million people were living with chronic HBV infection in 2019, with considerable morbidity and mortality (WHO, 2023). Early and accurate detection of HBV is essential for timely clinical intervention and monitoring.

Traditional diagnostic approaches include serological testing for hepatitis B surface antigen (HBsAg) and other viral markers, which remain essential for screening. However, molecular methods such as PCR allow direct detection and quantification of viral DNA, providing insight into viral replication and disease activity.

Biochemical parameters such as alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), and bilirubin serve as important indicators of hepatic inflammation and damage. Correlating HBV DNA status with these routine laboratory findings can deepen our understanding of disease progression and support clinical management.

Despite the high burden of HBV in India, limited studies have examined the relationship between HBV detected by molecular means and routine liver function markers in central India. Therefore, this study aimed to investigate HBV positivity detected by molecular methods and its correlation with laboratory findings among hepatitis B positive patients in a selected hospital in Ujjain, Madhya Pradesh.

MATERIALS AND METHODS

Study Design and Setting

A hospital-based cross-sectional descriptive study was conducted at SN Hospital, Ujjain, Madhya Pradesh, from June to December 2024.

Sample Size and Sampling Technique

A total of 120 patients diagnosed as hepatitis B positive by HBsAg screening were enrolled through consecutive sampling. Patients who had received antiviral therapy within the preceding six months or those with co-infection (HCV, HIV) were excluded.

Data Collection and Laboratory Investigations

Molecular Detection of HBV

Blood samples were collected under aseptic conditions for molecular analysis. HBV DNA was detected and quantified using real-time PCR (Roche/Abbott platform), with a lower limit of detection of 10 IU/mL.

Routine Laboratory Parameters

The following laboratory investigations were performed at the hospital central laboratory:

- **Liver Function Tests (LFTs):** ALT, AST, ALP, total bilirubin
- **Complete Blood Count:** including platelet count
- **Prothrombin Time (PT) and INR**

All procedures followed standard operating guidelines with regular quality control checks.

Statistical Analysis

Data were entered into SPSS version 25. Descriptive statistics were calculated for demographic and clinical variables. Pearson's correlation was used to explore the relationship between HBV DNA levels and biochemical/laboratory markers. A p-value < 0.05 was considered statistically significant.

RESULTS

Demographic and Clinical Features

Of the 120 HBsAg positive participants:

- **Male:** 78 (65%)
- **Female:** 42 (35%)
- **Mean age:** 39.5 ± 11.2 years
- **Family history of liver disease:** 18 (15%)

HBV DNA Positivity

Molecular analysis revealed:

- **HBV DNA detectable:** 92 (76.7%)
- **HBV DNA undetectable:** 28 (23.3%)

Laboratory Findings

Mean laboratory values across the cohort:

Parameter	Mean ± SD
ALT (IU/L)	84.7 ± 35.4
AST (IU/L)	78.9 ± 32.7
ALP (IU/L)	134.5 ± 54.8
Total Bilirubin (mg/dL)	1.9 ± 0.8
Platelet Count ($\times 10^9$/L)	154 ± 42

Parameter	Mean ± SD
PT (seconds)	14.2 ± 2.1

Correlation Between HBV DNA and Laboratory Parameters

Parameter	Correlation (r)	p-Value
ALT	0.64	< 0.001 **
AST	0.58	< 0.001 **
ALP	0.15	0.093
Total Bilirubin	0.10	0.212
Platelet Count	–0.42	0.002 **
PT	0.37	0.005 **

Key observations:

- A moderate positive correlation was seen between HBV DNA load and ALT/AST levels, indicating higher viral burden is associated with greater hepatocellular injury.
- Inverse correlation with platelet count suggests a relationship with impaired liver synthetic function.
- Total bilirubin and ALP did not show statistically meaningful correlations.

DISCUSSION

This study demonstrated that a substantial proportion (76.7%) of HBsAg positive individuals had detectable HBV DNA, underscoring the importance of molecular diagnostic evaluation in clinical practice.

Correlation with Liver Enzymes:

Significant positive correlation between viral load and ALT/AST aligns with previous research demonstrating that active viral replication causes hepatocellular inflammation

and leakage of liver enzymes (Lee et al., 2018). Elevated ALT and AST remain reliable biochemical markers of disease activity in chronic HBV infection.

Platelet Count & Coagulation:

The inverse relationship of HBV DNA with platelet count may reflect early hepatic fibrosis and impaired thrombopoietin production, as previously documented in chronic liver diseases (Singh et al., 2020). Similarly, significant correlation with prothrombin time highlights early compromise in liver synthetic capacity.

Non-Significant Markers:

Total bilirubin and ALP did not show significant associations with viral load — likely because these parameters may reflect cholestatic processes rather than direct hepatocellular damage.

Clinical Implications:

Molecular detection of HBV DNA should be integrated into routine diagnostics, as it provides actionable insights into disease activity and guides therapeutic decision-making. These findings support the combined use of virological and biochemical markers to monitor treatment response and disease progression.

Limitations

- Single-center study
- Lack of liver biopsy or imaging for fibrosis staging
- Cross-sectional design limits causality assessment

CONCLUSION

HBV positivity detected through molecular techniques correlated significantly with key laboratory indicators of hepatic injury, particularly ALT and AST. Molecular assessment of HBV DNA remains a critical component in clinical evaluation and management of hepatitis B patients. Future multicentric studies with longitudinal follow-up are recommended to better understand disease progression and therapeutic outcomes.

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