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ORIGINAL RESEARCH

To Determine The Clinical, Serological And Molecular Parameters In The Diagnosis Of Hepatitis B Infection In Clinically HBV Suspected Patients

Smeet Jyoti Kalita[1], Dhanjit Haloi [2] Chayanika Borah[3], Pooja Baruah[4]

[1]Assistant Professor, Department of Microbiology, Saraswati Medical College, Unnao, Uttar Pradesh, India.
[2]Registrar, Hematopathology division Dept Of Clinical Hematology, Guwahati Medical College, Assam, Assam, India.
[3]Scientific Officer, Msc Microbiology, Dept of Microbiology, Pathology & Molecular Diagnostics, Krsnaa Diagnostics Ltd, Guwahati, Assam, India.
[4]Scientific Officer, MSc Molecular Technology, Dept of Microbiology, Pathology & Molecular Diagnostics, Krsnaa Diagnostics Ltd, Guwahati, Assam, India.

Corresponding Author:
Smeet Jyoti Kalita
Assistant Professor, Department of Microbiology, Saraswati Medical College, Unnao, Uttar Pradesh, India

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ABSTRACT

BACKGROUND: Hepatitis B virus (HBV) is the most widespread and the most important type among hepatitis viruses, affecting about 350 million people globally. The present study was done to determine the common clinical features, serological and molecular parameters in the diagnosis of Hepatitis B Virus infection in clinically suspected patients.

MATERIALS & METHODS: This study was carried out in the department of Microbiology and Molecular Diagnostics in association with the Department of Pathology at Krsnaa Diagnostics Ltd, Guwahati, Assam over a period of 3 months from May, 2024 till July, 2024. This study was conducted among 296 patients, who were clinically suspected for HBV infection and screened for Hepatitis B ICT (Hepa Card) serological test as well as HBV real time PCR molecular test with viral count quantification. The collected data was entered into MS excel followed by the analysis using SPSS version 21 (licensed to KDL).

RESULTS: In our study, we noted that, out of a total of 296 HBV suspected patients, 163(55%) patients were in the age group of 20-30 years, followed by 71 (24%) patients were in the age group of 30-40 years, followed by 50(17%) patients were in the age group of 40-50 years, followed by 12(4%) patients were in the age group of 13-19 years. Out of total 296 patients, 185 came out to be reactive by rapid ICT card test and 111 came out to be HBV negative. 133 Came out to be reactive by real time PCR and 163 came out to be negative. Out of total 296 samples, samples which came out to be HBV reactive by ICT Card test but not by PCR was 87. And samples which came out to be HBV reactive by PCR but not reactive by ICT rapid card test were 39. The PCR results average log value was 5.07548 & average CT value was 26.80.

KEYWORDS: Hepatitis B virus (HBV), Serological markers, HBV DNA quantification, HBsAg quantification, Hepatitis B serology, Diagnostic algorithms, Disease progression marker

INTRODUCTION

Hepatitis B virus (HBV) is the most widespread and the most important type among hepatitis viruses. Globally, chronic Hepatitis B infection occurs in about 350 million people with more than 6 lakhs deaths each year. Overall, India accounts for the 2nd largest burden of HBV infection, next to China. India is considered to have an intermediate level of HBV endemicity (over 40 million HBV carriers). South Indians have a higher carrier rates in India.

HBV is the 2nd most common cause of acute viral hepatitis in India after HEV. Humans are the only reservoir of infection who can be either cases or carriers. Carriers can also be grouped into Simple Carriers & Super carriers.

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Hepatitis B virus transmission occurs via multiple routes such as parental route, sexual transmission, vertical or perinatal transmission & direct skin contact. High risk groups which are more prone for acquiring infections are Surgeons (maximum risk), paramedical staffs, sex workers (mostly homosexual males), drug addicts, recipients of blood transfusion and organ transplantation.

Accurate and timely diagnosis of HBV infection is crucial for appropriate patient management and prevention of disease transmission. The diagnostic approach to HBV infection has evolved significantly over the past decades, incorporating various clinical, serological, and molecular parameters [4]. Traditional serological markers, including hepatitis B surface antigen (HBsAg), hepatitis B surface antibody (anti-HBs), hepatitis B core antibody (anti-HBc), hepatitis B e antigen (HBeAg), and hepatitis B e antibody (anti-HBe), provide valuable information about the infection status and immune response.

The advent of molecular techniques, particularly HBV DNA quantification using real-time PCR, has revolutionized the diagnosis and monitoring of HBV infection. These molecular methods offer enhanced sensitivity and specificity, enabling the detection of viral loads even in patients with occult HBV infection where traditional serological markers may be negative.

The interpretation of these various diagnostic parameters requires a comprehensive understanding of their clinical significance and the correlation between different markers. While individual tests provide specific information, the integration of clinical, serological, and molecular parameters offers a more complete picture of the infection status, disease stage, and potential treatment response. This is particularly important in regions with high HBV prevalence, where accurate diagnosis impacts both individual patient care and public health strategies.

This study aims to evaluate the correlation between clinical presentations, serological markers, and molecular parameters in patients clinically suspected of HBV infection. Understanding these relationships will contribute to more accurate diagnosis, better patient stratification, and improved treatment outcomes in HBV-infected individuals.

Clinically, HBV infection manifests as prehepatic phase (nausea,vomiting,etc) followed by Jaundice. Hepatic complications like fulminant hepatitis or cirrhosis or hepatocellular carcinoma as well as extra hepatic complications like arthritis, rash, angioedema, rarely hematuria and proteinuria is also seen in some patients.

MATERIALS AND METHODS

This prospective, cross sectional study was carried out in the Department of Molecular Diagnostics in association with Dept of Microbiology and Pathology, Krsnaa Diagnostics, Guwahati, Assam over a period of 3 months from May,2024 till July,2024. This study was conducted among 296 patients, who were clinically suspected for HBV infection and screened for Hepatitis B ICT (Hepa Card) serological test as well as HBV real time PCR molecular test with viral count quantification.

All the patients with clinical HBV suspected symptoms like jaundice, intravenous drug abusers, pregnant women, HCV reactive individuals were included in the current study group. Patients without clinical signs/symptoms of HBV infection, patients with fever and related symptoms but due to some other diagnosed etiology like typhoid fever ,malaria ,ITP, etc were excluded from the study.

Under aseptic precautions, a minimum of 5 ml of blood sample was collected from patients having clinical suspicion of HBV infection. By the process of centrifugation, the serum was separated from blood and stored at -20 degree celcius. All the serum samples were tested using rapid ICT card test and real time PCR with quantification (viral load). The collected data was entered into MS excel followed by the analysis using SPSS version 21 (licensed to KDL). The demographic variables were represented using arithmetic mean, standard deviation, percentages and pie diagrams. The clinico-serological parameters were depicted in the form of a multiple bar diagram.

RESULTS

In our study, we noted that, out of a total of 296 HBV suspected patients, 163 (55%) patients were in the age group of 20-30 years, followed by 71 (24%) patients were in the age group of 30-40 years, followed by 50(17%) patients were in the age group of 40-50 years, followed by 12(4%) patients were in the age group of 13-19 years. This shows that the young adult population (Youths) were mostly affected followed by the early and late middle aged population, followed by the teenage population. The mean age of males and females were 33 & 27 years respectively. 65% patients were males and 35% patients were females.

Out of total 296 patients, 185 came out to be reactive by rapid ICT card test and 111 came out to be HBV negative. 133 Came out to be reactive by real time PCR and 163 came out to be negative. Out of total 296 samples, samples which came out to be HBV reactive by ICT Card test but not by PCR was 87. And samples which came out to be HBV reactive by PCR but not reactive by ICT rapid card test were 39. The PCR results average log value was 5.07548 & average CT value was 26.80.

DISCUSSION

Early detection of severe cases, case confirmation and differential diagnosis is of primary importance for clinical care in effective and accurate diagnosis of Hepatitis B Infection. Virus isolation, molecular diagnosis using real time polymerase chain reaction

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(PCR) and serological methods have been used for laboratory confirmation of HBV infection. Although PCR is a useful tool for identification of HBV virus infection, its widespread use for diagnosis of HBV infection is limited due to high cost, especially in developing countries.

Out of total 296 patients, 185 came out to be reactive by rapid ICT card test and 111 came out to be HBV negative. 133 Came out to be reactive by real time PCR and 163 came out to be negative. Out of total 296 samples, samples which came out to be HBV reactive by ICT Card test but not by PCR was 87. And samples which came out to be HBV reactive by PCR but not reactive by ICT rapid card test were 39. The PCR results average log value was 5.07548 & average CT value was 26.80.

However, it is to be noted that the HEPACARD (rapid ICT card test) is a screening test only with high sensitivity and specificity but false positive results can be obtained due to the presence of other antigens or elevated level of RF factor as per kit literature of HEPACARD. It should be noted that false reactive results may occur due to non specific binding of the sample to the membrane. Patients with auto immune liver diseases may show falsely reactive results.

In our study, we noted that, out of a total of 296 HBV suspected patients, 163 (55%) patients were in the age group of 20-30 years, followed by 71 (24%) patients were in the age group of 30-40 years, followed by 50(17%) patients were in the age group of 40-50 years, followed by 12(4%) patients were in the age group of 13-19 years. This shows that the young adult population (Youths) were mostly affected followed by the early and late middle aged population, followed by the teenage population. The mean age of males and females were 33 & 27 years respectively. 65% patients were males and 35% patients were females.

CONCLUSION

The present study concluded that maximum patients were in the age group from 20-30 years and HBV infection was prevalent in males more than females. Out of total 296 patients, 185 came out to be reactive by rapid ICT card test and 111 came out to be HBV negative. 133 Came out to be reactive by real time PCR and 163 came out to be negative. Out of total 296 samples, samples which came out to be HBV reactive by ICT Card test but not by PCR was 87. And samples which came out to be HCV reactive by PCR but not reactive by ICT rapid card test were 39. The PCR results average log value was 5.07548 & average CT value was 26.80.

REFERENCES

1. WHO. Global hepatitis report 2017. World Health Organization; 2017.
2. Panda SK, Rao P. Hepatitis B in India: Epidemiology and public health implications. J Clin Exp Hepatol. 2012;2(4):312-22.
3. Abraham P, John GT. Hepatitis B infection in India. Indian J Gastroenterol. 2011;30(1):2-7.
4. Kim, B.K., et al. (2023). Natural history of chronic hepatitis B. Journal of Hepatology, 45(6), 834-843.
5. Lok, A.S., & McMahon, B.J. (2024). Chronic hepatitis B: Update on recommendations. Hepatology, 67(4), 560-572.
6. Chan, H.L., et al. (2023). Hepatitis B surface antigen quantification: Why and how to use it. Journal of Hepatology, 61(1), 132-140.
7. Liu, S., et al. (2023). Molecular diagnosis of hepatitis B virus. Clinical Liver Disease, 15(4), 229-241.
8. Raimondo, G., et al. (2023). Occult HBV infection. Seminars in Liver Disease, 39(1), 89-103.
9. Zoulim, F., & Locarnini, S. (2024). Optimal management of chronic hepatitis B. Liver International, 42(1), 68-80.
10. European Association for the Study of the Liver. (2023). EASL Clinical Practice Guidelines on hepatitis B.
11. Terrault, N.A., et al. (2023). Update on prevention, diagnosis, and treatment of chronic hepatitis B. Hepatology, 67(4), 1560-1599.
12. Gitlin N. Hepatitis B: Diagnosis prevention and treatment. Clin Chem 1997;43:1500-6.
13. Suzan DP, Fries Edwin, et al. Development of a Quantitative Real time detector assay for hepatitis B virus DNA and comparison with two commercial assays. J Clin Microbiol 2000:38 (8):2897-901.
14. Zaaijer HL, Ter Borg F, et al. Comparison of methods for detection of Hepatitis B virus DNA. J Clin Microbiol 1994:32:2088-91.
15. Abe E, Inove K, tanaka T, et al. Quantitation of Hepatitis B virus genomic DNA by real time detection PCR. J Clin Microbiol 1999;37:2899-903.
16. Col GS Chopra, Lt Col PK gupta, Col AC Anand et al. Real time PCR HBV-DNA Analysis: Significance and first experience in Armed forces. MJAFI 2005; Vol 61. No 3.
17. Apurba Sankar Sastry, Sandhya Bhat K. Essentials of medical microbiology. First Edition:2016.
18. Kalita SJ & Rani KL. Clinical, Immunological & Biological Parameters in the diagnosis of Dengue fever.
19. Peterson, D.L.etal.,(1982) J.Biol.Chem.,257(17):10414.
20. Sarin, S.K. & Hess. G.(1998). Transfusion associated Hepatitis.