e-ISSN: 0976-822X, p-ISSN:2961-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2026; 18(8); 991-994

Original Research Article

Comparison of HBV DNA levels Among Newly Detected HBsAg-positive and Chronic Hepatitis B Patients in a Tertiary Care Hospital in Bengaluru

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Received: 07-06-2026 / Revised: 08-07-2026 / Accepted: 10-08-2026

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Conflict of interest: Nil

Abstract:

Background: Hepatitis B virus (HBV) is a major global public health concern with nearly a million new infections occurring annually. Around 240 million people are chronically infected with HBV worldwide, a sub-population of whom succumb to the consequent chronic liver diseases including cirrhosis and hepatocellular carcinoma. Comparing the quantitative levels of HBV DNA in new and chronic HBV cases may better inform strategies for effective antiviral treatment.

Objective: To study the serum HBV DNA levels in newly detected HBsAg-positive cases and chronic HBV patients.

Methods: A retrospective study was conducted on the serum samples of 45 HBV patients using real-time quantitative PCR at NVHCP State Laboratory, Bangalore Medical College & Research Institute from March 2021 to December 2021. The Abbott RealTime HBV Assay was used to determine serum HBV DNA levels. Data entry and analyses were performed on Microsoft Excel.

Results: Of the 23 newly detected HBsAg-positive patients, 12 (52.2%) cases turned up an undetectable HBV DNA level denoted as Target Not Detected [TND], 4 (17.4%) had a viral load < 100 IU/mL, 5 (21.7%) had < 10^5 IU/mL, and 2 (8.7%) had levels > 10^5 IU/mL. Among the 22 chronic HBV patients, there were 4 (18.2%) cases of TND, 2 (9.1%) < 100 IU/mL, 15 (68.2%) < 10^5 IU/mL, and 1 (4.5%) > 10^5 IU/mL which was notably higher than the assay seen in the newly detected cases.

Conclusion: Newly detected cases were seen to have lower viral loads and higher proportion of undetectable HBV DNA. Higher HBV DNA levels corresponds with the persistent HBsAg titres of chronic HBV and should be further evaluated in conjunction with other serum markers.

Keywords: hepatitis B virus; dna, viral; HBsAg protein; chronic hepatitis B.

DOI: 10.25258/ijcpr.18.8.150

Introduction

Although Hepatitis B virus (HBV) infection is entirely vaccine-preventable, it remains a major global public health concern that affects 0.9–1.8 million new individuals annually. While most adults infected with HBV make a full recovery, 5–10% of patients are unable to completely clear the virus and thus become chronically infected. [1] According to the World Health Organization, an estimated 240 million people worldwide were living with chronic HBV in 2024, with 1.1 million deaths occurring that year due to the development of liver cirrhosis and hepatocellular carcinoma in these patients.[2]

HBV is a DNA virus with a circular, partially double-stranded genome having four major gene reading frames – S, P, C, and X, that code for its

surface, core, polymerase, and regulatory proteins respectively. [3] Acute HBV infection is routinely diagnosed using serological tests that identify the hepatitis B surface antigen (HBsAg) in particular, as it is the primary protein of the viral envelope. [4]

With the hallmark of chronic HBV infection being the presence of HBsAg positivity for a period of at least 6 months, serum HBsAg level has also been considered an important marker to predict treatment outcomes in recent years. [5] The disappearance of HBsAg with seroconversion to anti-HBs antibodies is the most ideal therapeutic result in chronic HBV patients undergoing treatment. However, only 3–4% of patients are able to achieve this outcome, making it a less reliable marker for monitoring these patients. [6]

In contrast, serum HBV DNA assay which directly quantifies the viral load, is frequently used to categorize patients, predict long-term outcomes, make treatment decisions, assess antiviral treatment response, [7] and is largely considered a more accurate marker for chronic HBV monitoring. [6] However, periodic assays are typically difficult to carry out and have several drawbacks, including it being costly, labour-intensive, not consistently available in all laboratories, and lacking in consistency and standardization. [8]

This study was undertaken to compare the quantitative levels of HBV DNA in new HBsAg-positive and longstanding chronic HBV cases in order to help better inform treatment and monitoring strategies.

Methods

This retrospective study was conducted between March 2021 and December 2021, by analyzing the serum samples of 23 newly detected HBsAg-positive cases and 22 chronic HBV patients admitted in Victoria Hospital, Bengaluru. The samples were processed through real-time quantitative PCR (qPCR) at the National Viral Hepatitis Control Programme (NVHCP) State Laboratory affiliated with Bangalore Medical College & Research Institute using the Abbott RealTime HBV DNA assay. Data entry and descriptive analyses were performed on Microsoft Excel. Demographic data and HBV DNA levels were analyzed and presented as tables and graphs.

Results

A total of 45 serum samples were processed and analyzed with half the samples (n = 23) being drawn from newly detected HBsAg-positive cases and the rest from chronic HBV patients (n = 22). 77.8% of the study samples were collected from male patients [see Table 1] and the majority of cases (18, 40%) fell in the young adult demographic aged 21 to 40 years old [Fig.1].

Table 1: Baseline demographics

Parameter	**Newly detected HBsAg +ve** (N = 23)	**Chronic HBV** (N = 22)
Age, Mean ± SD	43.5 ± 17	37.5 ± 20.2
0–20 years	2	5
21–40 years	10	8
41–60 years	5	6
> 60 years	6	3
Sex, n (%)		
Male	20 (87%)	15 (68.2%)
Female	3 (13%)	7 (31.8%)

Of the 23 newly detected HBsAg-positive patients, 12 (52.2%) cases turned out to have an undetectable HBV DNA level denoted as Target Not Detected [TND], 4 (17.4%) had a viral load < 100 IU/mL, 5 (21.7%) had < 10^5 IU/mL, and 2 (8.7%) had levels > 10^5 IU/mL [Fig. 2].

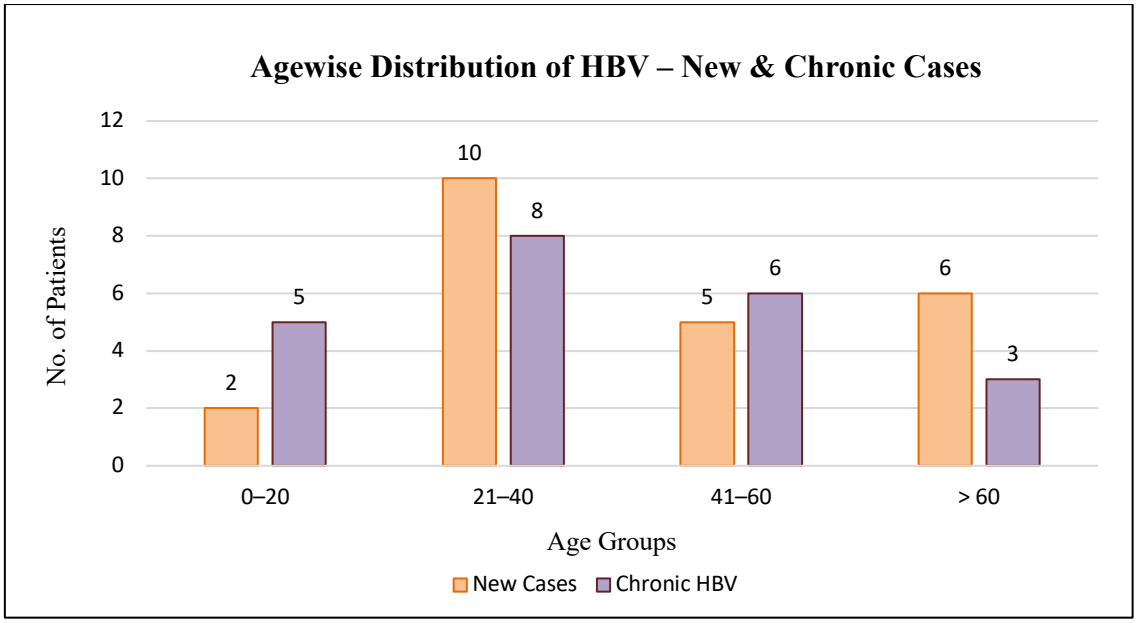

Figure 1: Agewise distribution of HBV – newly detected and chronic cases

Among the 22 chronic HBV patients, there were 4 (18.2%) cases of TND, 2 (9.1%) < 100 IU/mL, 15 (68.2%) < 10^5 IU/mL, and 1 (4.5%) > 10^5 IU/mL which was notably higher than the assay seen in the newly detected cases.

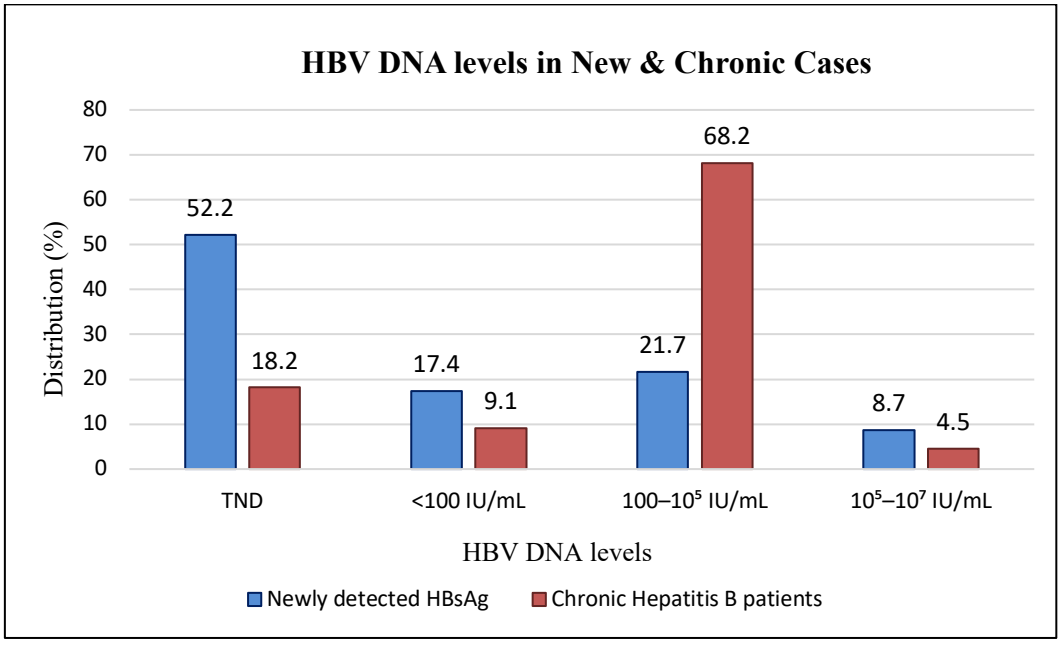

Figure 2: HBV DNA levels in newly detected and chronic cases

Discussion

Hepatitis B virus infection remains an important public health concern in today's world, with considerable variation in viral replication among infected individuals. While HBsAg is an important marker of HBV infection, HBV DNA provides a more direct measure of viral replication. In the present study, newly detected HBsAg-positive patients had a higher proportion of undetectable HBV DNA levels compared with chronic HBV patients (52.2% vs. 18.2%). Conversely, detectable HBV DNA was more frequently observed among chronic patients, particularly in the intermediate viral-load category.

Our findings are comparable with observations from previous studies demonstrating that the relationship between HBsAg and HBV DNA varies according to the phase of HBV infection and HBeAg status – an indicator of active viral replication and high infectivity. In a study of 173 patients with chronic HBV infection, a significant positive correlation between quantitative HBsAg and HBV DNA was

observed in HBeAg-positive patients ($r = 0.509$, $P < 0.001$), whereas the correlation was poor in HBeAg-negative patients. The authors concluded that quantitative HBsAg could reflect HBV DNA levels particularly in HBeAg-positive disease but could not reliably substitute for HBV DNA in HBeAg-negative patients. [9] Similarly, the landmark study conducted by Chan et al. in 2011 found that HBsAg correlated strongly with serum HBV DNA in HBeAg-positive chronic HBV infection, while the correlation was considerably weaker in HBeAg-negative patients. [10]

The higher proportion of undetectable HBV DNA among newly detected cases in our study may reflect differences in the stage of infection or level of viral replication at the time of detection. However, newly detected HBsAg positivity does not necessarily indicate recent or acute infection, as previously undiagnosed chronic infections may also be detected for the first time. Therefore, the lower HBV DNA levels observed in this group should not alone be interpreted as indicating a better prognosis.

The present study also highlights that HBsAg positivity and HBV DNA levels are not necessarily in accordance with each other. Since HBsAg was assessed qualitatively in our study and quantitative HBsAg levels were not measured, a direct statistical correlation between HBsAg concentration and HBV DNA could not be established. HBV DNA should therefore be interpreted along with other markers such as HBeAg, ALT and liver fibrosis assessment when evaluating patients and considering treatment.

The study is limited by its small sample size, retrospective design, and lack of additional virological and biochemical parameters. Furthermore, only a single HBV DNA measurement was available for each patient. Larger prospective studies incorporating quantitative HBsAg, HBeAg status and serial HBV DNA measurements would provide a better understanding of the relationship between these markers.

Conclusion

Newly detected HBsAg-positive cases demonstrated a higher proportion of undetectable HBV DNA levels compared with chronic HBV patients, while detectable HBV DNA was more frequent among chronic cases. These findings highlight the complementary role of HBV DNA quantification in the evaluation of HBsAg-positive individuals. However, HBV DNA should be interpreted alongside other virological, biochemical and clinical markers for appropriate disease assessment and treatment decisions.

Acknowledgement: The authors acknowledge Mr. Lakshmikanth Reddy, Technical Officer at NVHCP State Laboratory, Bangalore Medical College and Research Institute, Bengaluru for his valuable contribution to this study.

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