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Original Research Article

A Comparative Evaluation of Rapid Test and ELISA and Significance of Alanine Aminotransferase Levels in Patients of Hepatitis B and Hepatitis C at a Tertiary Care Centre in Western Uttar Pradesh

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Abstract

Background: Viral hepatitis remains a major global health concern, with Hepatitis B virus (HBV) and Hepatitis C virus (HCV) contributing significantly to chronic liver disease. Rapid diagnostic tests (RDTs) offer a practical alternative to enzyme-linked immunosorbent assay (ELISA) for screening, while alanine aminotransferase (ALT) serves as an important marker of hepatic injury.

Objective: This study aimed to evaluate the diagnostic performance of rapid tests using ELISA as the reference standard and to compare ALT levels between HBV and HCV patients.

Materials and Methods: This retrospective observational study was conducted at a tertiary care centre in UPUMS, Saifai, Uttar Pradesh, wherein samples were taken from 474 patients, of which 255 were reactive for HBV, and 219 were reactive for HCV by ELISA. The same samples had been subjected to rapid testing as well. ALT levels were categorized as normal (≤40 IU/L) or elevated (>40 IU/L). Sensitivity and positive predictive value (PPV) of rapid tests were calculated.

Results: The study population showed a significant male predominance (p-value 0.031) in the Hepatitis B group (62.7% males), while the mean age for hepatitis B and C was 41.6 ± 17.2 and 43.8 ± 14.6 years, respectively. Rapid tests demonstrated high sensitivity for both HBV (96.5%) and HCV (96.3%), with a PPV of 100% in both groups. A small proportion of cases were missed by rapid testing in both groups. Elevated ALT levels were observed in 10.6% of HBV patients compared to 73.1% of HCV patients, indicating a significant difference in biochemical profiles between the two infections.

Conclusion: Rapid diagnostic tests show high sensitivity and are useful for screening of HBV and HCV, particularly in resource-limited settings. However, the samples should also be subjected to ELISA testing, and both tests should be used in conjunction. The distinct ALT patterns observed highlight the importance of integrating biochemical assessment with diagnostic testing for better clinical evaluation and management of viral hepatitis.

Keywords: Hepatitis B, Hepatitis C, Rapid diagnostic test, ELISA, Alanine aminotransferase.

Introduction

Viral hepatitis continues to be a major global health challenge, with Hepatitis B virus (HBV) and Hepatitis C virus (HCV) contributing substantially to chronic liver disease, cirrhosis, and hepatocellular carcinoma worldwide. Despite advances in prevention and treatment strategies, a significant proportion of infected individuals remain undiagnosed, particularly in resource-limited settings, leading to delayed intervention and increased disease burden [1,2]. In India, HBV and HCV infections represent an important public health concern, with millions affected and a considerable risk of long-term complications if not detected early [3]. Early and accurate diagnosis plays a critical role in the management and control of viral hepatitis. Enzyme-linked immunosorbent assay (ELISA) remains the reference standard for detection; however, its widespread use is often limited by the need for laboratory infrastructure, trained personnel and longer turnaround times. In contrast, rapid

diagnostic tests (RDTs) offer the advantage of being simple, cost-effective, and suitable for point-of-care use, thereby improving access to screening, especially in peripheral healthcare settings [2,4]. Several studies have demonstrated variable sensitivity and accuracy of rapid tests in detecting HBV and HCV infections, highlighting the need for continued evaluation of their diagnostic performance in different clinical settings [5,6,7,8].

Along with virological diagnosis, biochemical parameters—particularly alanine aminotransferase (ALT)—play a crucial role in assessing hepatic injury and disease activity. ALT is widely used as a surrogate marker of hepatocellular damage and has been shown to correlate with disease severity in viral hepatitis [9,10].

Elevated ALT levels are frequently observed in HCV infection and are associated with progression to advanced liver disease and hepatocellular carcinoma [11,12]. However, ALT levels may remain normal in a subset of HBV-infected patients despite ongoing hepatic inflammation, which can complicate clinical decision-making [13]. This variability underscores the importance of understanding ALT patterns across different viral hepatitis infections.

Previous studies have explored the relationship between viral hepatitis and liver function parameters, demonstrating distinct biochemical profiles in HBV and HCV infections [14,15,16]. Additionally, ALT-based algorithms and combined biomarker approaches have been proposed to improve disease assessment and guide treatment decisions [17,18].

Given the increasing dependence on rapid diagnostic methods and the clinical significance of alanine aminotransferase (ALT) in disease monitoring, it is essential to evaluate both diagnostic performance and biochemical characteristics in real-world clinical settings. Such evidence can contribute to optimizing screening strategies and improving early detection and management of viral hepatitis.

However, despite the availability of rapid diagnostic tests and the recognized role of ALT as a marker of hepatic injury, there is limited data comparing the diagnostic performance of rapid tests with ELISA and assessing ALT patterns between Hepatitis B and Hepatitis C patients in routine clinical practice, particularly in Indian settings. Therefore, the present study was conducted to evaluate the diagnostic performance of rapid tests for the detection of Hepatitis B and Hepatitis C using ELISA as the reference standard, to compare alanine aminotransferase (ALT) levels between patients with Hepatitis B and Hepatitis C, and to assess the sensitivity of rapid diagnostic tests in detecting these infections.

Materials and Methods

This retrospective observational study was conducted in a tertiary care centre in UPUMS, Saifai, Uttar Pradesh, wherein a total of 474 blood samples were taken, of which 255 were from patients with HBV infection and 219 from patients having HCV infection over a period of one year. Data regarding the demographic variables such as age and gender, along with rapid test results, ELISA results, and alanine aminotransferase (ALT) levels, were recorded.

Inclusion Criteria: Patients of all age groups and both genders who were confirmed reactive by enzyme-linked immunosorbent assay (ELISA) and had corresponding rapid diagnostic test results available were included in the study.

Exclusion Criteria: Patients with incomplete laboratory records, missing rapid test or ELISA results, or indeterminate test findings were excluded from the analysis.

Principle: Screening for HBV and HCV infection was initially performed on all the samples using rapid immunochromatographic tests for the detection of Hepatitis B surface antigen (HBsAg) and anti-HCV antibodies using SENSA Hep-B ™ kits, respectively.

HBsAg utilises the principle of agglutination of antibodies/ antisera with respective antigen in an immuno-chromatography format, along with the use of nano gold particles as agglutination revealing agent. All samples were subsequently tested using an ELISA kit (HEPALISA J. MITRA). It is a solid-phase enzyme-linked immunosorbent assay (ELISA) based on the “Direct Sandwich” principle, which was considered the reference standard for diagnosis.

Interpretation of results

To assess the rapid test's performance, its results were compared with the results obtained from the ELISA method.

True positives were defined as cases where both rapid and ELISA tests were positive, and false negatives were cases where the rapid test failed to detect an infection confirmed by ELISA. Because this study included only those patients who had already tested positive by ELISA.

ALT levels were categorized using a standard cutoff value, with levels greater than 40 IU/L considered to be elevated and values of 40 IU/L or less considered normal (19). In both patient groups, ALT was recorded as a categorical variable (elevated or not elevated) using the same cutoff.

Cases with missing ALT values were excluded from ALT analysis.

Statistical analysis was performed using Microsoft Excel. Categorical variables were expressed as frequencies and percentages, and continuous variables were expressed as mean ± standard deviation. The sensitivity and positive predictive value (PPV) of rapid diagnostic tests were calculated using standard formulas.

Results:

A total of 474 patients were included in the study, with 255 cases of Hepatitis B and 219 cases of Hepatitis C. The study population showed a significant male predominance (p-value 0.031) in Hepatitis B groups (62.7% males). The mean age was comparable between the two groups, indicating a broadly similar demographic distribution (Table 1).

Table 1: Demographic Characteristics of Study Population

Variable	Hepatitis B (n = 255)	Hepatitis C (n = 219)	p- value
Age (years)			
Mean ± SD	41.6 ± 17.2	43.8 ± 14.6	0.13
Range	11 – 90	17 – 80	
Gender			
Male	160 (62.7%)	115 (52.5%)	0.031
Female	95 (37.3%)	104 (47.5%)	
Total	255 (100%)	219 (100%)	

Rapid diagnostic tests demonstrated a high detection rate in both Hepatitis B and Hepatitis C cases when compared with ELISA. Only a small proportion of cases were missed by rapid testing in each group, reflecting a consistently high level of agreement with the reference standard (Table 2).

Table 2: Distribution of Rapid Test and ELISA Results

Variable	Rapid Test (HBV) n (%)	ELISA (HBV) n (%)	Rapid Test (HCV) n (%)	ELISA (HCV) n (%)
Positive / Detected	246 (96.5)	255 (100)	211 (96.3)	219 (100)
Negative / Not Detected	9 (3.5)	0 (0.0)	8 (3.7)	0 (0.0)
Total	255 (100)	255 (100)	219 (100)	219 (100)

The overall diagnostic performance of rapid tests showed high sensitivity for both infections, with excellent positive predictive value. However, specificity and negative predictive value could not be determined, as all included cases were ELISA positive (Table 3).

Table 3: Diagnostic Performance of Rapid Tests

Parameter	Hepatitis B (%)	Hepatitis C (%)
Sensitivity	96.5	96.3
Positive Predictive Value (PPV)	100	100

A notable difference was observed in alanine aminotransferase (ALT) levels between the two groups. Elevated ALT levels were considerably more frequent among patients with Hepatitis C, whereas the majority of Hepatitis B patients had ALT values within the normal range (Table 4).

Table 4: Comparison of ALT Levels between HBV and HCV Patients

ALT Status	HBV (n=255) n (%)	HCV (n=212) n (%)
Elevated (>40 IU/L)	27 (10.6)	155 (73.1)
Normal (≤40 IU/L)	228 (89.4)	57 (26.9)
Total	255 (100)	212 (100)

Discussion

The present study evaluated the diagnostic performance of rapid tests in comparison to ELISA and assessed alanine aminotransferase (ALT) patterns in patients with Hepatitis B and Hepatitis C in a tertiary care centre of UPUMS, Saifai, and U.P.

A total of 474 patients were included in the study, with 255 cases of Hepatitis B and 219 cases of Hepatitis C. The study population showed a male predominance in both groups, which is similar to a study conducted at a hospital in Central India, where a highly significant male predominance was found among HBV-positive cases (71.8% males versus 28.2% females) and HCV-positive cases (79.5% males versus 20.5% females). [20] It can be behavioral, owing to greater frequency of high-risk activities such as injection drug use (IDU) and

greater social mobility [21,22,23]. Or it can be Biological, estrogen is thought to have a protective effect against liver inflammation and the development of hepatocellular carcinoma (HCC) in pre-menopausal women (MDPI, 2021; World Hepatitis Alliance, 2024). While the mean age group for hepatitis B was observed to be 40.2±12.6 years in a study done by Hamida et al. [24], which is similar to our study.

The findings demonstrated high sensitivity of rapid diagnostic tests for both HBV (96.5%) and HCV (96.3%), along with a marked difference in ALT profiles between the two infections. The high sensitivity observed in the present study is consistent with findings from previous studies evaluating rapid diagnostic assays. Stockdale et al. (2021) reported a sensitivity of 96% for HBsAg rapid diagnostic tests in a Malawian cohort, which closely aligns with the sensitivity observed for HBV in our study [5].

Similarly, Franzeck et al. (2013) demonstrated a sensitivity of 96% and specificity of 100% for rapid HBsAg detection in HIV-infected patients, further supporting the reliability of rapid tests in clinical practice [7]. In the context of HCV, Kumar et al. (2024) also reported high concordance between rapid card tests and ELISA, indicating that rapid assays can serve as effective screening tools, particularly in resource-limited settings [6]. These findings collectively reinforce rapid tests, while not replacing ELISA, thus providing a dependable first-line diagnostic modality and point of care testing.

However, it is important to note that a small proportion of cases were missed by rapid testing in both the HBV and HCV groups in the present study. Similar limitations have been highlighted in earlier literature. Clement et al. (2002) demonstrated that although rapid assays are useful, their performance may vary depending on antigen levels and disease stage [8]. Chevaliez and Pawlotsky (2018) also emphasized that while rapid tests improve accessibility, their diagnostic accuracy can be influenced by viral load and assay sensitivity thresholds [2]. This underlines the continued importance of confirmatory testing using ELISA, especially in clinically suspected cases.

A key finding of this study was the distinct difference in ALT patterns between HBV and HCV infections. Elevated ALT levels were significantly more frequent in HCV patients compared to HBV patients, where the majority exhibited normal ALT values. This observation is in agreement with previous studies highlighting the variable biochemical behaviour of these infections. Chen et al. (2026) reported that elevated ALT levels in chronic HCV infection are associated with increased risk of hepatocellular carcinoma, emphasizing the clinical importance of ALT monitoring [11]. Similarly, Humayun et al. (2011) demonstrated significantly higher ALT levels in HCV-infected individuals compared to healthy controls, supporting the association between HCV and active hepatocellular injury [12].

In contrast, the relatively normal ALT levels observed in many HBV patients in the present study are consistent with findings reported by Li et al. (2018), who noted that a substantial proportion of HBV-infected patients may have persistently normal ALT levels despite significant underlying liver inflammation [13]. This phenomenon has important clinical implications, as reliance solely on ALT levels may underestimate disease severity in HBV infection. Shimakawa et al. (2018) further highlighted the need for combined assessment strategies, incorporating ALT with other markers such as HBeAg, to improve clinical decision-making in HBV patients [17].

Differences in liver enzyme profiles between HBV and HCV infections have also been reported by Owais et al. (2025) and Anjum et al. (2015), who observed distinct patterns of liver function abnormalities in these infections [14,15]. Langohr et al. (2008) additionally demonstrated that liver enzyme alterations are more pronounced in HCV infection, particularly in the presence of co-infections, further supporting the findings of the present study [16]. These variations likely reflect differences in viral pathogenesis and immune-mediated liver injury between HBV and HCV infections.

From a clinical perspective, the findings of the present study underscore the complementary role of rapid diagnostic tests and biochemical markers in the management of viral hepatitis. While rapid tests facilitate early detection and screening, ALT provides insight into ongoing hepatic injury. As highlighted by WHO guidelines and global diagnostic strategies, integrating accessible diagnostic tools with biochemical assessment is essential for improving hepatitis control programs, especially in resource-constrained settings [1,4].

However, the present study had certain limitations. The inclusion of only ELISA-positive cases precluded the calculation of specificity and negative predictive value. Additionally, ALT was analyzed as a categorical variable, which may limit the assessment of its full clinical variability. Despite these limitations, the study provides valuable real-world evidence on the performance of rapid diagnostic tests and the biochemical differences between HBV and HCV infections in an Indian tertiary care setting.

Future studies should include ELISA-negative populations and larger multicentric cohorts to enable comprehensive evaluation of the specificity and overall diagnostic accuracy of rapid tests.

Additionally, integrating quantitative ALT assessment with advanced biomarkers or molecular assays may further enhance early disease detection and risk stratification in patients with viral hepatitis.

In the present study, specificity and negative predictive value could not be assessed due to the inclusion of only ELISA-positive cases. This methodological limitation is inherent to studies focusing on sensitivity analysis and has also been observed in similar diagnostic evaluations [5,6]. Nevertheless, the consistently high positive predictive value (100%) observed in our study reflects the strong agreement between rapid tests and ELISA in confirmed cases.

Conclusion

The present study demonstrates that rapid diagnostic tests for Hepatitis B and Hepatitis C show high sensitivity and strong agreement with ELISA, supporting their usefulness as effective screening tools in routine clinical practice, particularly in resource-limited settings.

At the same time, a distinct difference in ALT patterns was observed between the two infections, with elevated ALT levels being more common in Hepatitis C, while a substantial proportion of Hepatitis B patients exhibited normal ALT values.

These findings highlight that reliance on a single parameter may be insufficient for clinical assessment and underscore the need for a combined approach integrating both diagnostic testing and biochemical evaluation. Overall, the study emphasizes the role of accessible diagnostic strategies along with prudent biochemical interpretation in improving early detection and management of viral hepatitis.

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