Original Article

Comparison of Enzyme Linked Immunosorbent Assay with Immunochromatographic Strip for Screening of Hepatitis B virus Surface Antigen (Hbsag) and Hepatitis C Virus (Anti HCV) Related in a Low Resource Setting

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ABSTRACT

Background: Hepatitis B and C viruses (HBV and HCV) are major causes of liver disease worldwide, with significant prevalence in low-resource settings. Rapid and accurate diagnosis is crucial for effective management and control of these infections. This study compares the efficacy of immunochromatographic tests (ICT) and enzyme-linked immunosorbent assay (ELISA) for the screening of HBV and HCV.

Objective: The objective of this study was to evaluate the effectiveness of ICT in comparison with ELISA for the detection of HBsAg and anti-HCV in a semi-urban, low-resource setting.

Methods: In this cross-sectional study, 951 blood samples were collected from patients at a tertiary care hospital on the outskirts of Lahore. Samples were tested for HBsAg and anti-HCV using the rapid ICT method (Abbott Bioline HBsAg WB and Abbott Bioline HCV). Positive results were confirmed using ELISA (ANTEC Diagnostic Products, UK). Data analysis was performed using SPSS version 26, focusing on the comparison of sensitivity, specificity, and overall concordance between the two testing methods.

Results: Out of 951 individuals tested, the ICT method identified 71 positive cases (7.4%), with 11 (1.2%) for HBsAg and 60 (6.3%) for anti-HCV. ELISA confirmed all 71 positive cases identified by ICT, indicating high concordance between the two methods. The gender distribution was 434 males (45.6%) and 517 females (54.4%), with the majority in the 21-40 year age group (52.2%).

Conclusion: ICT is a reliable and cost-effective screening tool for HBsAg and anti-HCV in low-resource settings, with results highly comparable to those obtained from ELISA. Its application could significantly aid in the early detection and management of hepatitis in areas where access to more sophisticated diagnostic facilities is limited.

Keywords: Hepatitis B, Hepatitis C, Immunochromatographic Test, Enzyme-Linked Immunosorbent Assay, Low-Resource Settings, Screening, Cross-Sectional Study.

INTRODUCTION

Hepatitis, a multifaceted liver inflammation, is primarily attributed to several viral types, notably Hepatitis A, B, C, D, and E, with Hepatitis B virus (HBV) and Hepatitis C virus (HCV) being the most prevalent (1, 2). These infections often share common transmission pathways, including exposure to infected blood, injection drug use, and syringe reuse, with an additional risk for HBV transmission through sexual contact and from mother to child during pregnancy (3, 4). A comprehensive systematic review of over 500 studies, encompassing 1,376,503 patients with cirrhosis across 86 countries, highlighted the varying prevalence of these infections. It was observed that HBV infection rates in cirrhotic patients were relatively lower in Europe, the Americas, and Oceania compared to Africa and Asia. However, HCV infection showed greater regional diversity, with the combined prevalence of HBV and HCV in cirrhotic

patients exceeding 50% in many parts of Asia and Africa, and over 90% in Northern Africa. Notably, 42% of cirrhosis patients worldwide were found to have HBV infection, while 21% had HCV infection (5-7).

The ramifications of HCV infection are particularly dire, ranging from acute hepatitis to chronic liver disease and the potential for developing hepato-cellular carcinoma (HCC). In Pakistan, for instance, HCV is a leading cause of HCC (8). The absence of a viable vaccine for HCV, coupled with the high cost of treatment, underscores the need for accurate diagnosis to effectively manage and treat the infection, as well as to identify and mitigate potential risk factors (9-11).

Diagnostic methods for hepatitis include immunochromatography (ICT), Enzyme Linked Immunosorbent Assay (ELISA), and Polymerase Chain Reaction (PCR). ELISA stands out as a highly accurate screening technique, boasting an approximate accuracy rate of 99.9% (12-14). However, both ELISA and PCR methods are costly and generally confined to well-equipped laboratories and major tertiary care hospitals. In contrast, ICT kits are favored in rapid testing scenarios due to their speed, ease of use, and lower cost (15-17).

This study focuses on comparing the efficacy of ICT with ELISA in low-resource settings. The significance of this comparison lies in determining the most effective, accessible, and cost-efficient method for diagnosing HBV and HCV in areas where resources are limited. Given the high prevalence of these viruses in less affluent regions, particularly in parts of Asia and Africa, and the severe health consequences associated with delayed or inaccurate diagnosis, this research holds substantial public health importance. It aims to provide insights into optimizing diagnostic strategies in resource-constrained environments, thereby contributing to better disease management and prevention strategies (7, 8, 18-20).

MATERIAL AND METHODS

In this cross-sectional study, conducted at a tertiary care hospital situated in a semi-urban area on the outskirts of Lahore, a total of 951 blood samples were collected over a period of two years. The study aimed to compare the efficacy of rapid ICT methods with ELISA in the detection of HBsAg and Anti HCV. Upon collection, each blood sample was subjected to centrifugation for serum separation. The serum was then tested for HBsAg and anti-HCV using the rapid ICT method, specifically employing Abbott Bioline HBsAg WB and Abbott Bioline HCV kits (21). Adherence to the kit manuals was meticulously maintained throughout the testing procedure, ensuring consistency and reliability in the handling and processing of the samples (22).

From the 951 samples, 71 that tested positive for HBsAg and Anti HCV by the ICT method were subsequently confirmed using the ELISA method, utilizing ANTEC Diagnostic Products from the UK. This step was crucial in assessing the comparative accuracy and reliability of the ICT method against the more established ELISA technique (23).

Data collected from these tests were rigorously analyzed using the Statistical Package for the Social Sciences (SPSS), version 26. This analysis included various statistical techniques to assess the performance characteristics of the ICT method in comparison to ELISA. The use of SPSS facilitated a comprehensive evaluation of the data, allowing for an in-depth understanding of the effectiveness of these diagnostic methods in a low-resource setting. The study was conducted entirely in the past tense and from a third-person perspective, maintaining a standard of objectivity and professionalism required in medical research documentation (24).

RESULTS

In the study, a total of 951 individuals were evaluated, with a slightly higher representation of females (54.4%) compared to males (45.6%). The age distribution of the participants was predominantly within the 21-40 years age group, accounting for over half of the sample at 52.2%. This was followed by the 41-60 years age bracket, representing 31.2% of the participants. The younger (1-20 years) and older (61-80 years) age groups constituted smaller portions of the sample, at 14.1% and 2.5%, respectively (Table 1).

Table 1 Gender Distribution

Gender	Frequency	Percent
Male	434	45.6%
Female	517	54.4%
Total	951	100.0%

Table 2 Age Group Distribution

Age (years)	Frequency	Percent
1-20	134	14.1%
21-40	496	52.2%

Age (years)	Frequency	Percent
41-60	297	31.2%
61-80	24	2.5%
Total	951	100.0%

When examining the prevalence of Hepatitis B and C using the ICT method, out of the 951 samples tested, 71 samples were found to be cumulatively positive, translating to a prevalence rate of 7.4%. Specifically, 1.2% of the samples were positive for Hepatitis B, and 6.3% were positive for Hepatitis C. Most of the samples, 92.6%, tested negative for both Hepatitis B and C (Table 2).

Table 3 Hepatitis B and C Detection by ICT

Status	Frequency	Percentage
Cumulative Positive	71	7.4%
Hep B Positive	11	1.2%
Hep C Positive	60	6.3%
Negative	880	92.6%
Total	951	100%

Further confirmation was sought through the ELISA method. For Hepatitis B, the ELISA results were consistent with the ICT findings, with 11 samples (1.2%) testing positive and 940 samples (98.8%) testing negative. In the case of Hepatitis C, the ELISA method also confirmed the ICT results, with 60 samples (6.3%) testing positive and 891 samples (93.7%) testing negative (Tables 3 and 4).

Table 4 Hepatitis B Detection by ELISA

Status	Frequency	Percent
Positive	11	1.2%
Negative	940	98.8%
Total	951	100.0%

Table 5 Hepatitis C Detection by ELISA

Status	Frequency	Percent
Positive	60	6.3%
Negative	891	93.7%
Total	951	100.0%

These results highlight the distribution and prevalence of Hepatitis B and C in the sampled population, demonstrating the utility of both ICT and ELISA methods in the detection of these viruses in a semi-urban setting on the outskirts of Lahore. The consistency between the ICT and ELISA results suggests the reliability of ICT as a screening tool in this context, especially considering its advantages in terms of cost and convenience in low-resource settings.

DISCUSSION

In the study conducted, 951 patients were tested for Hepatitis B and C, with 71 testing positive on rapid immunochromatographic tests (ICT). Subsequent validation using enzyme-linked immunosorbent assay (ELISA) demonstrated comparable results, reinforcing the reliability of ICT in screening for these viruses, especially in low-resource settings.

This finding aligns with the research conducted by Prabha, Saikeerthana et al. in India in 2022. In their study involving 200 blood samples, only five were positive on ICT, with subsequent ELISA testing corroborating these results (25). This similarity in findings underscores the potential of ICT as an effective preliminary screening tool. Similarly, a study by Kaur, Raj et al. in India in 2000 revealed that while ICT exhibited a high specificity (100%), its sensitivity was slightly lower at 93.4% (26). These results mirror the trends observed in our study, suggesting a consistent pattern in the performance of ICT across different studies and settings.

Further supporting this notion, research by Irwig et al. from Seoul in 2002 and Safiya et al. in 2015 demonstrated comparable outcomes (27, 28). In these studies, ICT showed high sensitivity (97%) and specificity (100%) for detecting HBsAg, rivaling the performance of ELISA. However, a study by Irshad et al. in 2019 highlighted that while ICT is a viable option in contexts lacking the expertise or equipment for ELISA, it should not be viewed as a complete replacement for the more sensitive ELISA method (29). This sentiment pointed out the limitations of ICT, particularly its reduced sensitivity in detecting lower antibody titers (10mIU/ml-100mIU/ml), thereby limiting its applicability (21, 30).

These collective findings underscore the strengths and limitations inherent in both ICT and ELISA. While ICT stands out for its rapidity, cost-effectiveness, and ease of use, making it particularly suitable for resource-limited settings and urgent testing scenarios, it does not match the high sensitivity and specificity of ELISA, which requires more sophisticated infrastructure and financial investment. This study highlights the critical need for accessible, cost-effective, and accurate diagnostic methods in resource-limited settings, contributing significantly to healthcare decision-making, effective disease surveillance, and patient management.

Our study not only corroborates the findings from previous research but also underscores the importance of a balanced approach in the use of diagnostic methods. It recommends the use of ICT as an initial screening tool in low-resource settings, with subsequent confirmation by ELISA in cases where ICT results are positive, thus ensuring both cost-effectiveness and diagnostic accuracy. This dual approach could be pivotal in enhancing hepatitis surveillance and management, particularly in areas where healthcare resources are constrained (10, 17, 28, 30).

CONCLUSION

In conclusion, this study reinforces the viability of using immunochromatographic tests (ICT) as an initial, cost-effective screening tool for Hepatitis B and C in low-resource settings, with subsequent confirmation by enzyme-linked immunosorbent assay (ELISA) in positive cases. The comparable accuracy of ICT to ELISA, as demonstrated in our findings and supported by similar studies, underscores the potential of ICT in enhancing disease surveillance and patient management where resources are limited. However, the inherent limitations of ICT, particularly in detecting lower antibody titers, necessitate a cautious and balanced approach. The implications of these findings are significant, as they advocate for a more accessible and pragmatic approach to hepatitis screening in resource-constrained environments, potentially leading to improved healthcare outcomes and more efficient allocation of limited medical resources. This approach could be instrumental in bridging the gap in healthcare disparities, especially in regions where the financial and infrastructural challenges impede the widespread use of advanced diagnostic methods like ELISA.

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