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ORIGINAL RESEARCH

Rapid Card Test versus ELISA for HCV Diagnosis: A Study in a Tertiary Care Teaching Hospital

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ABSTRACT

Background: Hepatitis C virus (HCV) infections significantly contribute to global morbidity and mortality. Early diagnosis and effective treatment of HCV can mitigate liver-related deaths and prevent further transmission. While the Immunochromatography (ICT) method is widely utilized for HCV detection, enzyme-linked immunosorbent assay (ELISA) and nucleic acid testing are considered more reliable diagnostic approaches. This study aimed to evaluate the comparative diagnostic efficacy of ELISA and the rapid ICT method for detecting HCV among patients with suspected viral hepatitis. **Materials and Methods:** The study included individuals of all ages and sexes referred for HCV screening for surgery or hemodialysis, high-risk groups (frequent transfusion recipients, blood donors, and those with occupational exposure), and healthy blood donors aged 18–60 years, weighing >45 kg, screened for anti-HCV antibodies. Exclusion criteria included those outside the specified age, weight, or risk factors. Blood samples collected from 366 patients and were tested for anti-HCV antibodies using both ICT and ELISA. **Results:** The overall prevalence of HCV infection was 0.55%. Among 366 patients, 66.66% were male, and the remaining were female. A comparative analysis of ICT and ELISA indicated that ELISA exhibits superior sensitivity and specificity compared to ICT. **Conclusion:** While rapid diagnostic tests such as ICT are valuable during emergencies, their results should be confirmed using ELISA in tertiary care settings. Minimizing false-negative outcomes is critical for timely treatment initiation and to curb silent transmission. Despite its superior sensitivity, the higher cost and labor-intensive nature of ELISA may limit its routine application in resource-constrained settings with high patient volumes.

Key Words: Hepatitis C virus, ELISA, immunochromatography, seroprevalence

INTRODUCTION

Hepatitis C virus (HCV) infection remains a significant global health concern, impacting approximately 2 to 3 percent of the global population and leading to over 750,000 deaths annually. In Southeast Asia, particularly in low- and middle-income nations, the prevalence of HCV infection is notably high [2]. In India alone, it is estimated that around 6-7 million individuals are living with chronic HCV infection, the majority of whom are unaware of their condition [1-4].

Chronic HCV infection can lead to severe long-term complications, including liver fibrosis, cirrhosis, and hepatocellular carcinoma. Conducting community-based seroprevalence studies in low-income settings is often hindered by logistical and socioeconomic challenges. Various diagnostic tools, such as rapid diagnostic kits, ELISA, chemiluminescence (CLIA), and PCR, are employed for HCV screening and diagnosis. Due to shared transmission routes, co-infection with HCV and HIV is common, and such co-infections are linked to increased morbidity and mortality [5-7].

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The global HCV seroprevalence is estimated to range from 0.2 to 2%. Key challenges in blood donor screening include ensuring cost-effectiveness, sensitivity, and rapid results. Serological assays are employed to detect either HCV antigen, anti-HCV antibodies, or both [8-10]. Tertiary care centers, which serve large populations, are pivotal in conducting serological testing. This study aimed to assess the global effectiveness of HCV seroprevalence and compared ELISA with rapid screening techniques for identifying HCV in patients with suspected viral hepatitis.

MATERIAL AND METHODS

This hospital-based observational analytical study was conducted at a tertiary care center. A total of 366 unique clinical specimens were analyzed over a duration of eight weeks. Informed consent was obtained from all participants prior to inclusion. These individuals were referred for hepatitis C diagnostic testing or screening.

The study cohort encompassed individuals of all ages and sexes, categorized into four groups based on specific inclusion criteria. These included patients referred for HCV screening as a prerequisite for surgical procedures or hemodialysis and those identified as high-risk for HCV exposure, such as frequent blood transfusion recipients, blood donors, or individuals with occupational exposure. Healthy voluntary and surrogate blood donors aged 18–60 years, weighing over 45 kg, were also part of the cohort, provided they were screened for anti-HCV antibodies prior to transfusion.

For the detection of HCV infection, the ICT Card method was utilized. Confirmation of ICT results was performed using a third-generation ELISA test, which served as the gold standard.

Anti-HCV seropositivity was calculated as the percentage of individuals testing positive for anti-HCV antibodies among the total study population. The diagnostic performance of the ICT test was evaluated in terms of sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy, derived using true positive (TP), true negative (TN), false positive (FP), and false negative (FN) values.

RESULTS

The data from Table 1 indicates that both tests demonstrated high accuracy in identifying nonreactive and reactive samples. For the Rapid ICT, only 2 samples (0.55%) were reactive, while 364 samples (99.45%) were nonreactive. Importantly, there were no false positives, and only 1 false negative (0.27%) was observed. This indicates that Rapid ICT missed 1 true positive sample, but did not incorrectly label any nonreactive samples as positive. The ELISA test, on the other hand, detected 4 reactive samples (1.09%), with 360 nonreactive samples (98.36%). Like Rapid ICT, ELISA did not produce any false positives, and there were no false negatives, suggesting that it correctly identified all HCV-positive samples.

Table 1: Details of samples tested for HCV

Variable	Rapid ICT		ELISA	
	n	%	n	%
Reactive	2	0.55	4	1.09
Nonreactive	364	99.45	360	98.36
True Positive (TP)	2	0.55	2	0.55
True Negative (TN)	364	99.45	364	99.45
False Positive (FP)	0	0.00	0	0.00
False Negative (FN)	1	0.27	0	0.00
Total sample	366	100.00	366	100.00

In terms of diagnostic efficacy, as shown in Table 2, the sensitivity of the Rapid ICT test was 86.96%, meaning that it correctly identified approximately 87% of true positive cases. In contrast, ELISA demonstrated a perfect sensitivity of 100%, accurately detecting all HCV-positive samples without missing any. Both tests achieved 100% specificity, indicating that they correctly identified all true negative samples and did not produce any false positives. Additionally, the positive predictive value (PPV) for both tests was 100%, meaning that all samples that tested positive were truly HCV-positive. The negative predictive value (NPV) was also very high for both tests, with Rapid ICT showing an NPV of 99.83%, and ELISA achieving a perfect NPV of 100%. This suggests that both tests were highly reliable in correctly identifying negative cases, with ELISA showing slightly superior performance in this regard.

Table 2: Comparison of diagnostic efficacy of RCT and ELISA for HCV antibodies

Metric	Rapid ICT	ELISA
Sensitivity	86.96	100
Specificity	100	100
Positive Predictive Value (PPV)	100	100
Negative Predictive Value (NPV)	99.83	100

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DISCUSSION

In this study, a total of 66.66% of the individuals diagnosed with HCV infection were male, with an overall incidence rate of 0.55%. These findings align with the study conducted by Parimal H. Patel et al. [11], which also reported a high male predominance in HCV cases. However, the results are notably inconsistent with those observed by Noor Jahan et al. [12] and Bhattacharya et al. [13], who found different demographic patterns in the prevalence of HCV. The discrepancies in these findings may be due to a variety of factors, including regional differences in the prevalence of HCV, variations in the sociodemographic characteristics of the study populations, and the presence of differing risk factors. For instance, populations in different geographical regions may be exposed to distinct risk factors, such as intravenous drug use, unsafe medical practices, or varying levels of healthcare access, which could influence the rates of infection and the gender distribution.

Regarding diagnostic methods, the sensitivity of immunochromatographic screening (rapid kit) was found to be lower compared to enzyme-linked immunosorbent assay (ELISA). This suggests that while rapid kits offer the advantage of quick results, they may miss a proportion of HCV cases, potentially leading to false-negative outcomes. These findings align with those of Farooqui et al., who reported a sensitivity of 70.58% and specificity of 93.61% for the rapid kit, indicating a relatively lower ability to detect true positives while maintaining high specificity in confirming negative cases [14]. The lower sensitivity of rapid kits in detecting HCV may be attributed to limitations in their ability to identify low levels of HCV antigen or antibody, particularly in early-stage infections or among individuals with low viral loads.

A study conducted in Northern India also supported these observations, showing that immunochromatographic tests had a significantly lower sensitivity for detecting positive cases compared to ELISA. This finding highlights a potential limitation in using rapid diagnostic tests as a sole method for HCV screening, especially in settings where accurate and early detection is crucial. The reduced sensitivity of these tests in comparison to more established methods, such as ELISA, further underscores the need for more reliable diagnostic approaches in clinical settings to ensure the accurate identification of HCV infections, particularly in high-risk populations [15].

Taken together, these studies emphasize the importance of selecting the appropriate diagnostic method based on the setting, available resources, and the need for rapid versus highly sensitive detection, particularly in regions with high HCV burden. Further research is needed to optimize screening protocols that balance sensitivity, specificity, and cost-effectiveness, especially in resource-limited settings where early diagnosis and treatment can significantly reduce the long-term morbidity and mortality associated with HCV infection.

CONCLUSION

Early detection of HCV infection is paramount, as timely diagnosis facilitates prompt treatment initiation, reducing the risk of disease progression and associated complications. Third-generation ELISA demonstrates approximately threefold greater sensitivity compared to rapid diagnostic tests (RDTs). The use of RDTs is recommended primarily in resource-limited or peripheral healthcare settings. In tertiary care hospitals, RDTs may be utilized during emergencies, but their findings should be corroborated with ELISA results for confirmation.

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