**ORIGINAL RESEARCH**

# Role of Rapid Card Test and Enzyme-Linked Immuosorbent Assay for Detection of HCV Infection in Patients Attending a Tertiary Care and Teaching Hospital, in the Doda area of Jammu and Kashmir

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**ABSTRACT**
Hepatitis C virus (HCV) infections are a major contributor to morbidity and mortality worldwide. Early detection and curative treatment of HCV can reduce the risk of liver-related mortality and serve to prevent transmission of new infections. Although HCV detection by the Immunochromatography (ICT) method is one of the most popular methods, enzyme linked Immuosorbent assay (ELISA) and nucleic acid test methods are considered more reliable. The detection of an HCV infection in suspected patients utilizing a dependable rapid technique therefore takes hours. **Aims and Objective:** The current investigation was conducted to assess the comparative efficiency of ELISA and fast screening (ICT) procedure for the diagnosis of HCV in suspected cases of viral hepatitis. **Methods & Materials:** Blood samples from patients from different IPD and OPD departments were analyzed for anti-HCV antibodies by both ICT and ELISA, with ELISA being the gold standard in the Department of Microbiology, Govt. Doda Medical College. **Result:** The overall incidence of HCV was observed to be 0.55%. Of a total of 3623 patients, 2420 (66%) were male and the remainder (33%) were female. The overall performance activity of ICT with ELISA is presented in Table 1. The ELISA methodology appears to have better sensitivity and specificity compared to ICT. **Conclusion:** Rapid diagnostic tests can be employedduring emergency hours, but their outcomes must be followed by ELISA test results at a tertiary care hospital. Reporting of false negative results should be minimized to offer a quick link to treatment initiation and avoid silent transmission of infection. Although EIA has a higher range of sensitivity, its cost and laborious process may make it less desirable than ICT in our country of limited resources and high caseload.

**Key words:** Hepatitis C virus, immunochromatographic test strip, ELISA, seroprevalence.



## INTRODUCTION

Hepatitis C virus (HCV) infection, a major global health problem, affects between 2 and 3 percent of the world's population and causes over 700,000 deaths annually [1]. In low- and middle-income Southeast Asian countries, the burden of HCV infection is significant [2]. It is estimated that about 6 million people suffer from chronic HCV infection in India alone, most of whom are unaware of their infection status [3,4]. Long-term effects of chronic HCV infection are liver fibrosis, cirrhosis and hepatocellular carcinoma [5]. It is challenging to conduct community-based seroprevalence studies in a poor country due to logistical and socioeconomic challenges. A variety of laboratory techniques, including rapid kits, ELISA, chemiluminescence (CLIA), and PCR, are used today for HCV screening and diagnosis [6]. Since HCV and HIV share similar routes of transmission, co-infection rates are high and are associated with higher morbidity and mortality as well [7]. HCV seroprevalence varies between 0.2 and 2% worldwide. Determining the seroprevalence of HCV in the general population is currently the focus [8,9]. Cost-effectiveness, sensitivity and the need for

quick responses are the three main problems in blood donor screening procedures. Through the use of serological assays, we can identify HCV antigen, anti-HCV antibody, or both [10]. A tertiary care facility serving a sizable population serves as a critical hub for serological testing. This study compared the effectiveness of HCV seroprevalence worldwide between 0.2 and 2%. The general seroprevalence of HCV is currently being determined. This study compared ELISA and rapid screening techniques for identifying HCV in probable patients with viral hepatitis treated at the Doda, J&K Tertiary Care Hospital.

## MATERIALS AND METHODS

This hospital-based observational analytical first analysis was done in our tertiary care facility. A total of 3623 consecutive non-repeated clinical specimens were employed in this investigation over a period of one and a half months. Each patient gave informed consent. 2420 (66%) of the 3623 patients were patients of any age and both sexes from the IPD and OPD of this hospital who have been recommended to undergo a hepatitis C diagnostic test or a hepatitis C screening, while the remaining 33% were female. Patients from the different departments of this hospital (both IPD and OPD) of all ages and both sexes who have received recommendations to have a diagnostic hepatitis C test or a Hepatitis C screening before any surgical procedure or hemodialysis, ii) who were either exposed, e.g. B. Frequent recipients or donors of blood or blood products, or with high risk exposure, such as hospital or treating OPD of various departments (especially gastroenterology/liver clinic and general medicine exposed casual and professionally, v) both voluntary and surrogate donors who are said to be healthy Subjects who met the donation requirements (aged 18 to 60 and weighed more than 45 kg) who were told to be tested for anti-HCV antibodies before receiving a transfusion were implemented in the study. In the ongoing study, ICT (Hepa Card) was applied to identify HCV infection. The gold standard for confirming ICT results was a third generation ELISA (Erba Lisa Gen3).

## DATA ANALYSIS

Anti-HCV seropositivity (%) was calculated as (presence of anti-HCV/total population) x 100. The specificity, sensitivity, positive predictive value (PPV), negative predictive value (NPV) and correctness of the ICT test for HCV infection were measured from true positive (TP), true negative (TN), false negative (FN) and false positive (FP). Sensitivity was expressed as TP/(TP + FN) x100, specificity as TN/(TN + FP) x100, NPV as TN/(TN + FN) x100, PPV as TP/(TP + FP) x100 and die Accuracy as (( TP+ TN)/sample size) x100.

## RESULT

A total of 3623 blood samples from the department of different IPD and OPD patients were tested for anti-HCV antibodies. HCV was found to be widespread in all populations at 0.55%. The majority of patients were between 19 and 70 years old. Two thousand four hundred and twenty (66%) of the population were males and 33% were females. Table 1 gives an overview of the overall performance of ICT and ELISA. Compared to ICT, the ELISA methodology seems to offer a higher level of sensitivity and specificity.

**Table no1: Evaluation of the HCV Rapid ICT Kit using ELISA.**

| Evaluation of HCV rapid ICT kit with ELISA | Total sample (n=3623) | Reactive | Nonreactive | True positive (TP) | True negative (TN) | False positive (FP) | False negative (FN) |
|---|---|---|---|---|---|---|---|
| Rapid ICT | 3623 | 17 | 3606 | 20 | 3603 | 00 | 03 |
| ELISA | 3623 | 20 | 3606 | 20 | 3603 | 00 | 00 |

ICT=immuno chromatography test, HCV=hepatitis C virus

The overall sensitivity, specificity, positive predictive value, and negative predictive value of the ICT-based test were 86.95%, 100%, 100%, and 99.3%, respectively. In comparison, the ELISA methodology showed 100% sensitivity, specificity, positive predictive value and negative predictive value

**Table no.2**: **Comparison of sensitivity of ELISA and RCT techniques HCV antibodies**

| | ELISA Test (%) | Rapid Test (%) |
|---|---|---|
| sensitivity | 100 | 86.95 |
| specificity | 100 | 100 |
| positive Predictive Value | 100 | 100 |
| negative Predictive value | 00 | 99.3 |

## DISCUSSION

Males accounted for a total of 66% of individuals with HCV infection, which had a incidence rate of 0.55%. These results agree with studies by Parimal H. Patel *et al*. [11] but vastly dissimilar from those reported by Noor Jahan *et al*. and Bhattacharya *et al*. [12] These discrepancies may outcome from different geographical regions and the involvement of different patient groups with different risk factors.

Immunochromatographic screening (rapid kit) has lower sensitivity (85.7%) compared to ELISA (100%), but specificity rates are the identical in both situations.

According to a report by Farooqui et al. the sensitivity was 70.58% and the specificity 93.61% [13]. According to a investigation from Lahore, Pakistan, the sensitivity of ICT showed a poor detection incidence of positive cases compared to ELISA. [14,15].

## CONCLUSION

As a result, we can say that 3rd generation ELISA is 3.0 times more sensitive than RDT (86.95%). Only in peripheral healthcare settings or in situations where resources are limited should RDT be recommended. In a hospital giving tertiary care, RDT should be employed during emergency hours, but the conclusion of this test should be followed by those of an ELISA test. Early diagnosis of HCV infection is critical as timely care and treatment is required. The probability of chronification and the occurrence of problems is also reduced by starting therapy in good time. False negative results pose a risk of disease spread and silent transmission as HCV is a very serious infection for the community.

Although EIAs offer the highest level of sensitivity, they are less preferred due to their cost and lengthy process. Rapid tests are a good substitute for ELISA in time-sensitive blood banks. Due to the higher specificity of some rapid kits and the reduction of false negatives, the performance of the rapid kits is satisfactory. ICT can be used in blood banks with limited infrastructure because it is fast and affordable. It can only be used for initial screening; nevertheless, it cannot be the main criterion for diagnosis. To determine the veracity of such devices for their claims, additional study with a larger sample size and more advanced techniques. Further research is needed to establish the validity of such devices in terms of their sensitivity and specificity, using larger samples and more sophisticated methods.

## HUMAN AND ANIMAL RIGHTS

No Animals were used in this research. All human research procedures followed were in agreement with the ethical standards of the committee responsible for human experimentation (institutional and national), and with the Helsinki Declaration of 1975, as revised in 2013.

## CONSENT FOR PUBLICATION

Written informed consent was obtained from all patients were include in this study.

## CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

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