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Comparative Evaluation of Rapid Card Test and Enzyme Linked Immunosorbent Assay for the Detection of Hepatitis C Virus Antibody in a Tertiary Care Hospital

Lalbiakdiki*, Sneha Mohan, Tarana Sarwat and Dimpi Nath

Department of Microbiology, Central Laboratory, School of Medical Sciences & Research, Sharda University, Greater Noida

**Corresponding author*

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A B S T R A C T

This study aimed to compare the Rapid card test with Enzyme linked Immunosorbent assay and to detect the seroprevalence of anti- HCV infection in Greater Noida. Hepatitis C Virus (HCV) belongs to family Flaviviridae and genus Hepacivirus. It is a single stranded, enveloped, positive sense RNA virus.Liver is the main site of infection and is transmitted via- blood and blood. This study was conducted to compared between a Rapid card test and Enzyme linked Immunosorbent Assay (ELISA) for detecting Hepatitis C Virus antibody in a human serum. The present study was conducted in the Serology section Department of Microbiology, School of Medical Sciences & Research, Sharda University for a period of 12 months (1st Nov 2020-31st Oct 2021) to comparative evaluate the detection of Hepatitis C Virus antibodies by rapid card test and ELISA. A total of 386 samples were taken for the test. Out of 386 samples, only a total of 92 samples were selected randomly for ELISA test with 46 negatives and other 46 positives samples from rapid test. Out of 46 negatives sample by rapid 1 turns out to be positive and from the 46 positive ICT samples 5 turns out to be negative by ELISA. The sensitivity and specificity of ICT was 90% and 97.61% respectively the PPV was 97.82% and the NPV was 91.30% when compare with ELISA. The seroprevalence was found to be 1.72%. Hence, anti HCV screening can be preferably done by Rapid Card test followed by a supplemental ELISA and Polymerase Chain Reaction for further confirmation.

Introduction

Hepatitis C Virus (HCV) belongs to family Flaviviridae and genus Hepacivirus. It is a single stranded, enveloped, positive sense RNA virus. HCV protein possesses three structural proteins, the nucleocapsid core protein C, two enveloped glycoproteins E1 and E2. Six non-structural NS proteins NS2, NS3, NS4, NSHB, NS5A and NS5B (Majunder and Shetty, 2017). Hepatitis C virus was identified in 1989 as the main etiological agent of non-A, non-B hepatitis (NANBH) accounting for greater than 90% of post- transfusion hepatitis cases. They are considered to be the major cause of acute chronic hepatitis, liver cirrhosis and hepatocellular carcinoma throughout the world (Mandawat and

Matur, 2019). HCV being a blood borne virus. Transmission of HCV infection mainly occurs on drug users (sharing of infection equipment), reuse or inadequate sterilization of medical equipment like needle and syringes, transfusion of unscreened blood and blood products, parental transmission (infected mother to child) and sex (Pyadala *et al.*, 2016). Several other parenteral risk factors include tattoos, needle-stick accidents among healthcare workers.

Needle - stick accidents from HCV viremic patients which lead to HCV transmission in 3-10% of the exposed people (Ijaz Hayder *et al.*, 2012). According to World Health Organization (WHO) approximately 170 million people are infected with HCV worldwide.

More than 500,000 people died each year due to complications of hepatitis C. In most of the infected people, more than 70% the disease becomes chronic which leads to chronic hepatitis, 5-20% develops cirrhosis, and 1–5% died from cirrhosis or liver cancer (Khan *et al.*, 2010; Maheshwar *et al.*, 2017).

Several screening tests are employed for testing anti-HCV to determine a final sero-status. The immuno-chromatographic test (ICT) is rapid, simple, and used along with rapid determination, in settings with limited facilities when rapid results are required.

The most major concern in utilizing rapid screening test is that these tests should provide a high degree of sensitivity, reasonable level of specificity so as to minimize false positive and false negative result (Zarski *et al.*, 2003).

However due to the high false positivity rate of HCV with ICT based methods, Enzyme Linked Immunosorbent Assay (ELISA) is considered more reliable than ICT based for HCV diagnosis. Both these test devices accurate fall in the range of 95-99%, 97-100% for specificity and sensitivity (Khanejra *et al.*, 2021). The purposed of this study was to compare the sensitivity and specificity of Immunochromatography technique (Rapid Card Test) with that of ELISA which is considered a Gold Standard technique for the detection of HCV antibody.

Materials and Methods

The present study was conducted in Department of Microbiology, Central Laboratory, School of Medical Sciences & Research (SMSR) for a period of 12 months (1st Nov 2020-31st Oct 2021). It was a cross- sectional observational study. The study population comprised of two groups- Group A and Group B. The Group A subjects were anti- HCV seropositive whereas Group B subjects were anti-HCV seronegative. We included all blood samples for HCV received in the serology section of Microbiology Department, Central Laboratory. The haemolyzed, lipemic, insufficient, unlabelled, leaked samples or samples received in wrong vacutainer were excluded from the study.

Sample collection and Processing

Approximately, 5ml of the blood was drawn aseptically using a sterile disposable syringe and needle. The drawn blood was transferred aseptically to a sterile red capped vacutainer vial. The blood was allowed to clot at the room temperature.

Subsequently the clot was centrifuged at 10,000 rpm for 10 minutes. The separated serum in this manner was pipetted and transferred into a sterile eppendorf tube. The serum sample was appropriately labelled and stored at 2-8°c until the test was performed. The sera were subjected to anti- HCV test, and anti-HCV ELISA test. Any sera which were found to be turbid, haemolytic or lipemic was discarded.

Patient Serum Samples

It was a Cross-sectional observational study. A total of 13939 blood samples were received in serology laboratory for anti- HCV test. 386 were randomly selected to be included in the study with 193 positive samples and 193 negative samples. HCV antibodies in the serum were detected by using commercially available 4th Generation HCV TRI-

DOT rapid kit. Manufacturer- Diagnostic Enterprises.

Erba Lisa HCV 3rd generation ELISA KIT.

Manufactured by Erba Mannheim Transasia Biomedicals Ltd. B-11, OIDC, Ringanwada, Daman-396210, India.

The test was performed according to the manufacturer's instructions.

Statistical Analysis

Ethical clearance was obtained from the Institutional Ethics Research Committee, SMS&R, Sharda University before the commencement of the study. All the results were recorded in tabular and graphical format. Assessment of sensitivity, specificity, positive and negative predictive values and concordance were estimated.

Results and Discussion

A total of 13939 samples received in serology laboratory for anti- HCV test. 386 were randomly selected to be included in the study with 193 positive samples and 193 negative samples by rapid card test.

Selection of samples for elisa testing

Out of 386 samples, 92 samples were selected randomly for ELISA test. Two groups were created- Group A and Group B. In group A 46 positive and in group B 46 negative samples were included for ELISA testing.

OPD/IPD Wise Distribution of Samples (Total no = 92)

Out of 46 positive samples taken, 31 sample were from IPD and 15 were from OPD and out of 46 negative samples, 32 were from IPD and the remaining 14 patients were from OPD. As shown in (Table 02, Figure 01).

Comparative Evaluation of Rapid Card Test and Elisa for Anti- HCV Detection

92samples with 46 positive samples (Rapid card Test) and 46 negative samples (Rapid card Test) were taken for ELISA testing. Out of 46 positive samples 1 turn out to be negative by ELISA and out of 46 negative samples by ICT 5 samples turned out to be positive by ELISA. As shown in (Table 03. Figure 02)**.**

Parameters of studied by using ELISA as gold standard

Thus, present study results confirm that the ICT could be used in the settings where ELISA is not an option. Various parameters were calculated by using following appropriate mathematical formula:

Sensitivity: TP / (TP + FN) x 100

Specificity: TN / (TN + FP) x100

Positive Predictive Value: TP / (TP + FP) x100

Negative Predictive Value: TN / (TN + FN)

LR+= sensitivity / 1 - specificity

LR- = 1 – sensitivity / specificity

Accuracy = TP+TN / (TP+TN+FP+FN)

When the sensitivity and specificity were calculated by using the formulae, the sensitivity and specificity of ICT was 90% and 97.61% respectively.

Thus, from present study, the positive concordance was 97.82% and the negative concordance was 91.30% when compare with ELISA.

Seroprevalence of HCV by Rapid Card Test

A total of 13946 samples tested by Rapid 240 turn out to be positive and 13706 were negative. The present study shows 1.72% of positive seroprevalence. (Table 05, Figure 04)

Hepatitis C virus (HCV) is a global healthcare problem which cause liver infection. It is a single stranded, enveloped, positive-sense RNA virus belonging to family Flaviviridae. HCV was discovered in 1989. HCV being a blood borne virus. Transmission of HCV infection mainly occurs on drug users (sharing of infection equipment), reuse or inadequate sterilization of medical equipment like needle and syringes, transfusion of unscreened blood and blood products, parental transmission (infected mother to child) and sex (Kumiko *et al.,* 1996).

Approximately 2-3%, with about 210 million are infected with HCV in Worldwide (Baldo *et al.,* 2008). Several techniques have been used for the diagnosis of HCV infection based on the detection of anti-HCV IgG antibodies as a screening by methods like Enzyme linked immunosorbent assay (ELISA), immunochromatography assays (ICT) and positive result verified by more specific supplemental assay such as recombinant immunoblotting assay (RIBA) and HCV RNA polymerase chain reaction (PCR) viral load in clinical practices. Chemiluminescence immunoassay (CLIA) are being widely used now for screening anti-HCV antibodies, particularly in high volume clinical laboratories for detection of anti-HCV antibodies (Majunder and Shetty, 2017).

In present study ELISA was compared with the Rapid card (TRI- DOT) for the detection of anti HCV. ELISA was taken as the Gold standard for serological testing of anti HCV. Samples, which were tested by ELISA maximum were from IPD.

The sensitivity of Rapid card test was 90%, specificity 97.61%, PPV and NPV were 97.82% and 91.30% respectively with references to ELISA. The sensitivity of ICT is low as compared to ELISA which is comparable to other study by Ijaz *et al.,* in 2012 showing 86% sensitivity,96% specificity, 95% PPV and 87% NPV respectively also, Singh *et al.,* in 2017 shows 95.24% and 99.7% sensitivity and specificity, 90.90% and 99.87% PPV and NPV respectively.

In the present study prevalence was found to be 1.72%, which was low, when compared with other study conducted by Koate *et al.,* in 2005, showing 2.9% of prevalence in Nigeria. However, a study from South Haryana, showed 3.0% HCV prevalence which was much higher than the present study (Dimple *et al.,* 2021).

The lower prevalence was found in the present study which might be due to the pandemic scenerio which lessened the sample to be tested for HCV.

The limitation of this study is that out of the 386 sample only 92 samples were tested by ELISA. For more specific results all the samples should have been tested. In present study sex, age group, risk group, socio economy and the high-risk group were not mentioned, if it was mentioned then these would have been more helpful for the clinicians to correlate with the treatment.

So, we can conclude that, an ideal rapid test is a boon in time-saving and can be easily performed by any trained health care worker at any time of need. It can definitely be preferred as a screening test, not only before haemodialysis, but also for any other emergency surgery. It is cost effective also.

Hence anti HCV screening can be preferably done by Rapid Card test followed by a supplemental ELISA and Polymerase Chain Reaction for further confirmation.

Table.1 Showing the no. of samples performed by ELISA

RAPID CARD TEST POSITIVE	**46**
RAPID CARD TEST NEGATIVE	46
TOTAL	92

Table.2 Showing OPD/IPD wise distribution of samples (Total no. = 92)

Rapid card test	IPD	OPD
Positive samples (46)	31(67.39%)	15(32.61)
Negative samples (46)	32(69.56%)	14(30.43%)

Table.3 Showing Comparative Evaluation of Rapid Card Test and ELISA for HCV

	HCV		
	ELISA POSITIVE	**ELISA NEGATIVE**	**TOTAL CASES**
Rapid Positive	45	1	46
Rapid Negative	5	41	46
Total	50	42	92

Table.4 Parameters studied by using ELISA as gold standard

Test Method	Sensitivity	Specificity	NPV	P PV	Positive Likelihood ratio	Negative Likelihood ratio	Diagnostic accuracy
Rapid card	90%	97.61%	91.30%	97.82%	30	0.07	93.47%

Table.5 Showing Seroprevalence of HCV by Rapid Card Test

RAPID CARD	RESULTS
POSITIVE	240(1.72%)
NEGATIVE	13,706(98.28%)
TOTAL	13,946

Fig.1 Showing OPD/IPD wise distribution of samples (Total no. = 92)

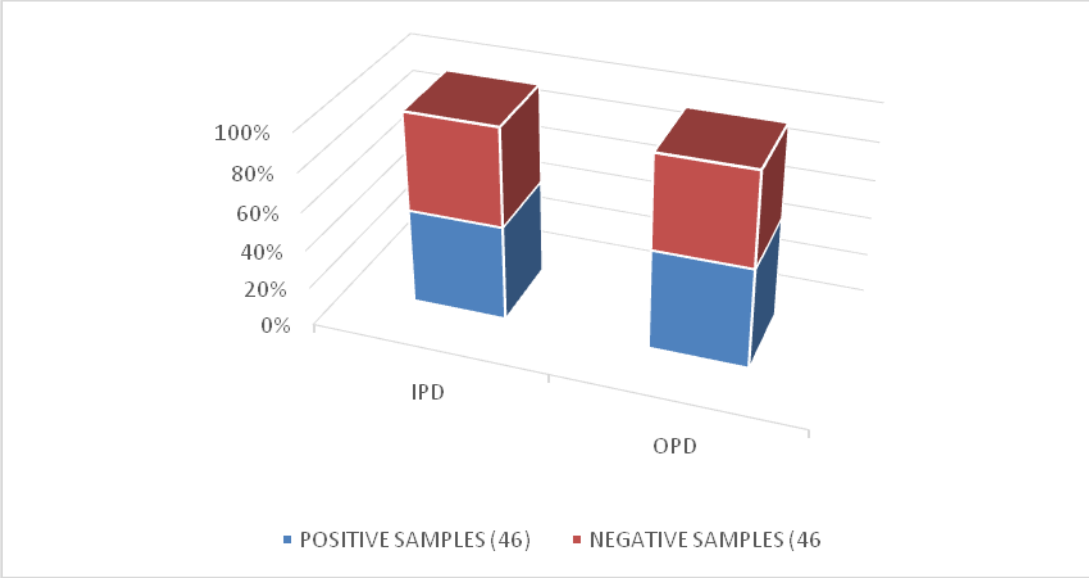


Fig.2 Showing parameters studied by using ELISA as gold standard

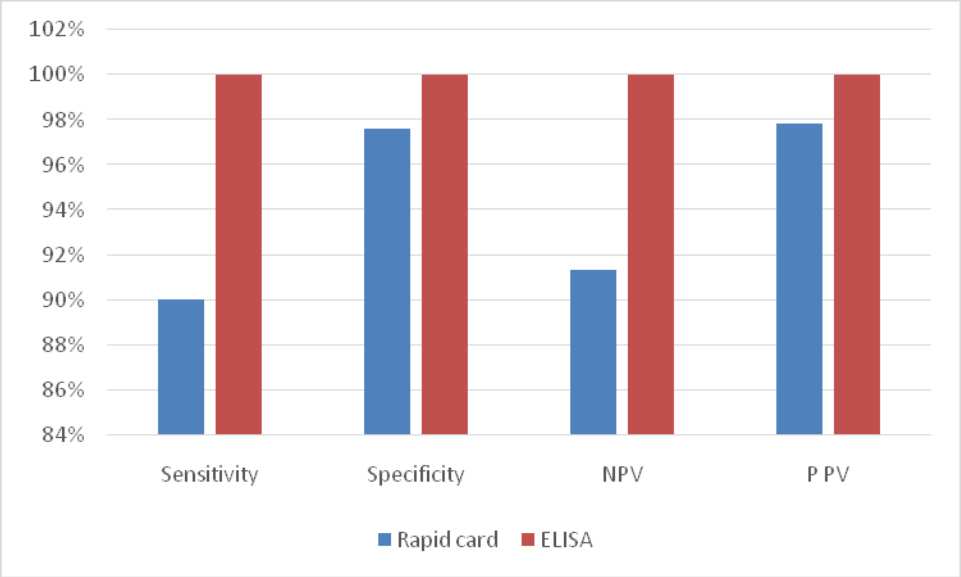
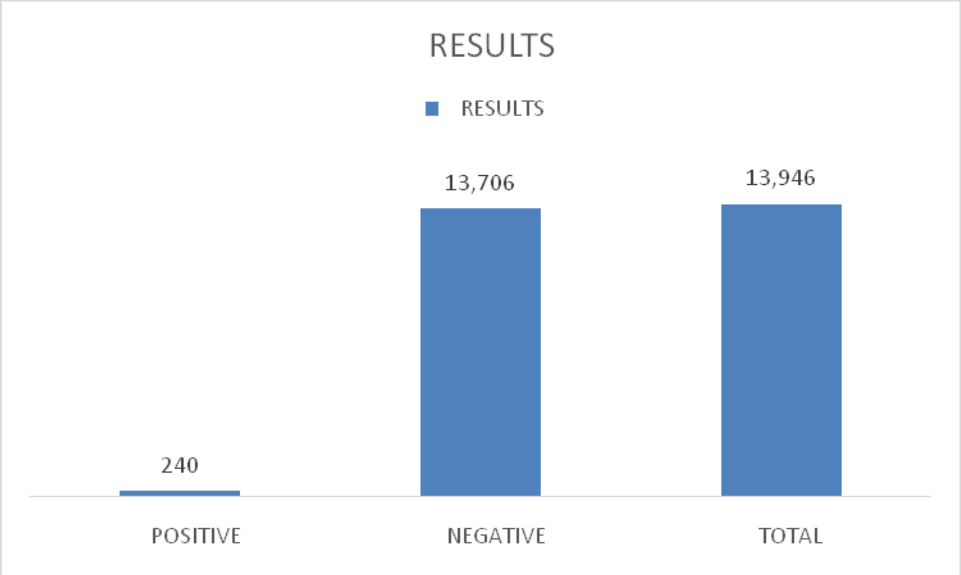


Fig.3 Showing seroprevalence of HCV by Rapid card test.



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