

EFFICACY OF RAPID IMMUNOCHROMATOGRAPHIC TEST IN THE DIAGNOSIS OF HEPATITIS C.



Medicine

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ABSTRACT

Introduction: The Global Health Sector Strategy on Viral Hepatitis calls for elimination of viral hepatitis by 2030. For expediting the diagnosis of Hepatitis C cases, a largescale screening program for Hepatitis C by using a good point of care test becomes essential.

Aims & objectives: To assess efficiency of rapid test to ELISA in detection of anti HCV antibody in the diagnosis of Hepatitis C.

Method: A prospective, cross sectional study was conducted for a period of one year at a tertiary care hospital and included 600 subjects of all age groups. Five ml of blood was collected for testing Hepatitis C by both rapid (HCV Trustline, Chennai, India) & ELISA (MERILISA HCV, Gujarat, India) tests. Results were analyzed statistically.

Result: Anti HCV antibody rapid test gave a sensitivity of 82% & specificity of 100% with a positive predictive value of 100% & negative predictive value of 99.66%, taking ELISA as the gold standard.

Conclusion: The Rapid test (HCV Trustline) was found to be a good point of care test in the diagnosis of Hepatitis C and could be used in healthcare setup where rapid and accurate results are desired.

KEYWORDS

Hepatitis C, Rapid test, ELISA, Anti HCV antibody test

INTRODUCTION:

Hepatitis C (HCV) virus infection occurs worldwide. Every year, 3-4 million people are infected with HCV with more than 3.5 lakhs deaths and 170 million chronic carriers [1]. Hepatocellular carcinoma, liver failure and cirrhosis of liver are some of the complications caused by this virus. Hence, an early diagnosis will help in preventing the morbidity and mortality associated with this infection.

For diagnosing HCV, many tests are available, such as ELISA, Recombinant Immunoblot Antibody assay, HCV core antigen assay, RT PCR and Rapid Immunochromatographic tests. Compared to the other tests described, a good Rapid Immunochromatographic test would be very useful whenever there is an urgent need to know the patient's serostatus with respect to Hepatitis C. A rapid Immunochromatographic test can conveniently be used even in peripheral health care centres as performance of the test does not require any special infrastructure nor expertise. Thus, the present study was carried out to find out efficiency of a rapid test for anti HCV antibody in the diagnosis of Hepatitis C.

AIMS & OBJECTIVES:

To assess efficiency of rapid test to ELISA in detection of anti HCV antibody in the diagnosis of Hepatitis C in the general population at a tertiary health care center.

MATERIALS AND METHODS

The present study is a prospective, cross sectional study and conducted at Department of Microbiology of a tertiary care hospital in Mumbai for a period of one year (1st May 2017- 30th April 2018) and included 600 subjects. Sample size was calculated by following formula

$$\text{Sample size (n)} = Z_{1-\alpha/2}^2 \frac{P(1-P)}{d^2}$$

Where,

n = sample size, P = anticipated population proportion, d = absolute precision required on either side of the proportion, α = error, Z = constant.

Inclusion criteria:

The inclusion criteria of the study were to include patients of all age groups and both sexes coming with clinical suspicion of hepatitis, namely complaints of fever with nausea, vomiting, joint pain, loss of appetite, jaundice and pain in abdomen. These patients were either registered at the outpatient department (OPD) or were patients admitted in wards and had been advised to undergo Hepatitis C screening.

Exclusion criteria:

Patients who had previously tested positive for Hepatitis C and patients

who refused to give consent for the study were excluded from the study.

Ethics permission:

The study was initiated after taking approval from the Institutional Ethics Committee.

Methodology:

Study group: The study group included different segments of the general population with varied risk factors and co morbidities. All the patients in the study group satisfied the inclusion criteria.

Study procedure:

All patients (n= 600) satisfying the inclusion criteria were included in the study. A detailed clinical history was taken. The patients were explained about the test procedure.

Collection of specimen:

Five milliliter of fasting blood sample from each patient was collected in a plain vacutainer. The serum was separated in sterile vials and then tested by rapid immunochromatographic test and ELISA for Hepatitis C, as per kit literature. ELISA was taken as the gold standard for comparison of the rapid test in consideration.

Known serum specimens that had tested positive & negative were included as external positive & negative quality controls respectively.

The details of rapid test kit and ELISA used in the present study are as follows:

- Rapid Immunochromatographic test- HCV Trustline Athenese Dx Pvt. Ltd. (Chennai, India) of lot no. F0205171, expiry date 01/05/2019.

The rapid test is a qualitative test based on the principle of lateral flow immunochromatographic assay for the qualitative detection of anti HCV antibody. 30-45 μ l of sample of serum or plasma is to be used for the test. The results are available in 15 minutes. As per the manufacturers kit insert the relative sensitivity is of 99.17% and relative specificity 99.5%.

- ELISA - HCV MERILISA kit of Meriline diagnostic Pvt. Ltd. (Gujarat, India) of lot no. MI011816, expiry date 2019/03.

MERILISA is a sandwich type of ELISA used to detect anti HCV antibody.

The results were analyzed statistically by Fischer's exact test and odds ratio.

RESULT AND DISCUSSION:

In the present study, all the 600 specimens were tested by both rapid and ELISA test with proper quality controls and the results were noted.

Mean age of Hepatitis C positive cases in the present study were found to be 14.18yr. A male preponderance was observed in the study.

In the present study, a total of 11 cases were positive for Hepatitis C (Table 1), of which

- 9 cases were positive by both rapid test and ELISA. (true positive)
- 2 cases were negative by rapid test but positive by ELISA. (false negative)
- No case was seen to be negative by rapid test and positive by ELISA.

As seen above, two blood specimen were positive by ELISA but negative by the rapid tests used in the study. The discrepancy in the results of rapid test which gave two false negative results may be due to inadequate coating of the antigens, nature of the antigens used and genetic heterogeneity of the virus as suggested by VP Torane et al. [2]

Table – 1 Comparison of Hepatitis C Rapid test with ELISA.

HCV Rapid	HCV ELISA test		Total
	Positive	Negative	
Positive	9(1.8%)	0(0%)	9(1.8%)
Negative	2(0%)	589(98.2%)	591(98.2%)
Total	11(1.8%)	589(98.2%)	600(100%)

Table 2 - Statistical parameters of Rapid test for Hepatitis C

Sensitivity	$a/(a+c)$	0.8182
specificity	$d/(b+d)$	1.0000
positive likelihood ratio	$sen/(100-sp)$	0.0083
negative likelihood ratio	$100-sen/sp$	99.1818
diagnostic accuracy	$(a+d)/(a+b+c+d)$	0.9967
Positive predictive value (PPV)	$a/(a+b)$	1.0000
Negative predictive value (NPV)	$d/(c+d)$	0.9966

Thus, sensitivity of rapid test used in the present study was found to be 82% while specificity was found to be 100%.

Positive predictive value of rapid test was found to be 100% and negative predictive value was found to be 99%.

The time taken for performing the rapid test and ELISA was 15 minutes and approximately 2 hours respectively. No special infrastructure was required for the rapid test as compared to ELISA which requires ELISA reader, ELISA washer, etc for performing ELISA. Performing and then reading and interpreting the results of ELISA required skilled personnel compared to that for the rapid test

Table 3- Comparative studies of Rapid tests for Hepatitis C.

Study by	Year	Kit name/ Manufacturer	Sensitivity	Specificity
Muthiah K. et al. [3]	2011	Span Diagnostics Ltd. India	85.7%	100%
Farooqui M. et al. [4]	2015	Virucheck Anti HCV (Orchid Biomedical System.)	70.58%	93.61%
Pyadala N. et al. [5]	2015	Genomix One step Hepatitis C antibody rapid test kit	100%	100%
Swapna S. et al. [6]	2016	Flavicheck HCV (Qualpro Diagnostics, Goa, India)	93.9%	NA*
Present study	2018	Trustline HCV Athenese Dx Pvt. Ltd. (Chennai, India)	82%	100%

(*Remarks: NA- Not available)

Different immunochromatography assay (ICA) based rapid tests used for anti HCV antibody detection in the serum may not have the same accuracy index and varies with the different manufacturers (Table 3). There is 100% specificity observed in three of four studies including the present one. The sensitivity of Rapid tests in the various studies ranged from 70.58% to 100%.

On comparing the sensitivity and specificity of the rapid test used in the present study with the values given in the kit literature of the test, there

was concordance of the rapid test used in the present study with respect to specificity but no concordance was seen with respect to the sensitivity observed. Hence, it is essential to assess and evaluate any new test kit with a gold standard to find out its actual efficacy.

A study by Muthiah K et al. [3] at Tirunelveli in 2011 had observed similar findings as compared to present study with respect to a positive predictive value of 100% & negative predictive value 99%. Another study by Farooqui MK. Et al. [4] observed a lower positive predictive value of 66% & a negative predictive value of 94% with the rapid immunochromatographic test used by them for diagnosing Hepatitis C. Hence, choosing the rapid test with the highest sensitivity and specificity is essential to help detect cases of Hepatitis C more accurately for optimum management of cases.

In May 2016, the World Health Assembly endorsed the Global Health Sector Strategy on Viral Hepatitis 2016–2021. This strategy calls for the elimination of viral hepatitis as a public health threat by 2030 by reducing new infections by 90% and mortality from viral hepatitis by 65%. For HCV infection, this is sought to be achieved through (i) reduction of transmission and (ii) heightened diagnosis and treatment [7].

India is the second most populous country, with approximately 1.3 billion population [7]. For expediting the diagnosis of Hepatitis C cases and achieving the target of the World Health Assembly, a large scale screening program for Hepatitis C to assess the burden of this infection with reasonable accuracy is required. Hence, it becomes essential to have a good point of care test for screening. The test has to be rapid, accurate, does not require skilled personnel nor an elaborate infrastructure and which could be performed both in field or tertiary care settings.

CONCLUSION:

In the present study, the Rapid test (Trustline HCV) for diagnosis of Hepatitis C was found to have a sensitivity of 82% and a specificity of 100% making it a good point of care test in the diagnosis of Hepatitis C especially in healthcare setup where quick results are desired. Although, confirming the results with ELISA would be advisable.

Rapid antibody detection test have maximum utility in casualty, emergency laboratories and in intensive care setups not only in tertiary care hospital but also in primary health care centers.

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