

Comparative Evaluation of Elisa and Rapid Screening Techniques for the Diagnosis of HCV amongst Suspected Viral Hepatitis Cases Attending Tertiary Care Hospital, Kolkata

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Abstract: HCV is a blood borne virus that attacks the liver and can cause chronic hepatitis, liver cirrhosis (27%) and liver cancer (25%). So detection of HCV infection in suspected patients by a reliable rapid method is a need of hours. The present study was conducted to assess comparative efficacy ELISA and rapid screening techniques (ICT) for the diagnosis of HCV amongst suspected viral hepatitis cases. A total of 2512 non-repetitive blood samples from patients of various indoor and OPD department were screened for anti-HCV antibody by both ICT and ELISA taking ELISA as a gold standard. The overall prevalence of HCV was found to be .95%. The overall sensitivity and specificity rate of ICT based test was 85.7% and 100% respectively. In comparison ELISA methodology showed both 100% sensitivity and specificity. Although EIAs shows better degree of sensitivity but due to its cost and as it is a time taking procedure it mayless preferable in comparison to ICT in our resourse limited country with high volume of case load.

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I. Introduction

HCV infection is a major public health problem with an estimated global prevalence of HCV is 3%.^[1,2] There are about 180 million carriers and approximately 4 million people annually are newly infected^[2,3]. HCV is a single stranded positive-sense RNA virus, 9.6kb in length and belongs to family flaviviridae and genus Hepacivirus. HCV is a blood-borne virus, and well known risk factors for HCV transmission includes injection drug abuse,^[4,5] blood/blood product transfusion. Hepatitis C virus (HCV) can cause asymptomatic infection.[1] The seroprevalence of HCV globally ranges between 0.2-2%. Presently, determination of the seroprevalence of HCV in general population is apriority.^[2,3] Community based seroprevalence studies are difficult to conduct in a developing country because of socioeconomic hurdles and logistic difficulties. A tertiary care hospital catering to the needs of a large population represents an important centre for serological surveys. In this study, comparative evaluation was made of ELISA and Rapid Screening Techniques for the diagnosis of HCV amongst suspected viral hepatitis cases attending tertiary care Hospital, eastern India.

II. Materials and Methods

This hospital based observational analytical pilot study was conducted in our tertiary care set up. A total of 2512 no of consecutive, non-repetitive clinical samples were included in this study over a period of one and half month. Informed consent of each patient was taken. Out of these 2512 patients 1708 (68%) were male and remaining were female. , patients of all age group and both sexes of different department of this Hospital (both IPD and OPD)who were advised to undergo Hepatitis-C diagnostic-testing or for Hepatitis-C screening i) before any surgical procedure/Haemodialysis, ii)who were either exposed like repeated blood or blood product receiver or donors or with high risk exposure like IV drug users, undergone tattooing ii) suspected and symptomatic Hepatitis patients as admitted in various wards of this Hospital or attending OPD of different departments(specially Gastro enterology/Liver clinicand general medicine,who are accidentally and occupationally exposed,v) both voluntary and replacement blood donors who were apparently healthy persons and qualified the donation criteria (age 18 to 60 years and having body weight more than 45 kg) and were advised to be screened for anti-HCV antibody prior to transfusion was included in the study. In present study we used ICT (IMMU CHECK) for detection of HCV infection. For the reconfirmation of ICT results we used 3rd generation ELISA as gold standard (HEPA SCAN).

III. Results

A total of 2512 blood samples from patients of the Department of various indoor department and OPD screened for anti-HCV antibody. The overall prevalence of HCV was found to be .95%. Majority of the patients were in the age group between 19 to 70 years. One thousand and seven hundred (68%) were male and rest (32%) were female. The overall performing activity of ICT with ELISA was depicted in the table one. ELISA methodology seems to have better sensitivity and specificity level in comparison with ICT.

Table no1. Evaluation of HCV rapid ICT kit with ELISA.

Evaluation of HCV rapid ICT kit with ELISA	Total sample (n=2512)	Reactive	Nonreactive	True Positive (TP)	True Negative (TN)	False Positive (FP)	False Negative (FN)
Rapid ICT	2512	20	2492	24	2488	00	04
ELISA	2512	24	2488	24	2488	00	00

ICT=Immuno chromatography test, HCV=Hepatitis C Virus

The overall sensitivity, specificity, positive predictive value and negative predictive value of ICT based test were 85.7%, 100%, 100% and 85.7% respectively. In comparison ELISA methodology showed 100% sensitivity, specificity, positive predictive value and negative predictive value.

Table no.2 Sensitivity comparison of ELISA and RCT techniques HCV antibody

	ELISA test (%)	Rapid Test (%)
Sensitivity	100	85.7
Specificity	100	100
Positive predictive value	100	100
Negative predictive value	100	85.7

IV. Discussions

The overall prevalence rate of HCV infection was .95% with male preponderance (62%). This findings is in accordance with the study of Parimal H. Patel *et al* ^[6]but quiet different with the findings of Noor Jahan et al and Bhattacharya *et al*.^[7]These differences may be due to different geographical areas and involvement of different patients group with different risk factors.

The immuno chromatographic screening (rapid kit) has a lower sensitivity (85.7%) in comparison to ELISA (100%) but the speficity rates are same in both cases. A study from Lahore Pakistan reported Sensitivity of ICT, which showed a low detection rate of positive cases in comparison with the ELISA.^[7,8] A study from Lahore reported very low sensitivity (44% to 66%) but specificity was fairly high (93% to 100%).^[8] A study from Lahore reported 2.35% false positive cases on ICT as compared to ELISA.^[9,10] An-other study from Pakistan showed 0.15% false positive results on ICT in blood donor screening.^[12] A study of Hepatitis C in HIV Patients from Cameroon showed 9.1% false positive results in control gro-up and 6.3% in HIV positive patient using ELISA as the gold standard.^[14]

V. Conclusion

Data indicate that fewer than half of those infected with HCV may be aware of their infection. The findings suggest that more intensive efforts are needed to identify and test persons at risk for HCV infection.

The estimated number of persons with chronic hepatitis C virus (HCV) infection increased from 2.7 million during 1988-19941 to 3.2 million during 1999-2002. Many infected persons, however, are unknown to the healthcare system because they may be asymptomatic for years, have not been tested for HCV, and only seek medical care for their infection when complications occur as part of the natural progression of untreated infection. Currently, HCV infection is the etiology most frequently associated with newly diagnosed chronic liver disease, and the effect on healthcare utilization is high. The number of healthcare visits associated with hepatitis C increased in ambulatory care settings during 1992-20035 and has remained at a high level through at least 2006.

In all the above studies specificity is consistent with our results, but due to sample size difference variation is seen in term of sensitivity which is not the major concern, because in hospital setup false positive result will be better than a false negative results. Inadequate coating of the antigens on the surface of the immune filter or the nature of Antigens used in rapid tests and ELISA can affect the results. Further-more genetic heterogeneity can affect the serological response. Fall in sensitivity of ICT can also be explained by chance variation, inadequate representation of antigen on rapid device.

Although EIAs shows maximum degree of sensitivity but due to its cost and as it is a time taking procedure it is less preferable. In blood banks where time is the major issue rapid tests is the good substitute of ELISA. Specificity of some rapid kits has increased due to the use of synthetic antigens and due to decrease false negative results therefore the performance of the rapid kits are satisfactory. ICT can be used in blood banks with limited facilities because it is rapid and cheap. It can be used for initial screening only but it could not be the only criteria for diagnosis. Further research with improved sample size and higher techniques are required to found the credibility of such devices for their sensitivity and specificity.

References

- [1]. Hepatitis C [Internet]. World Health Organization. 2018 [cited 30 October 2018]. Available from: <http://www.who.int/news-room/fact-sheets/detail/hepatitis-c>
- [2]. GLOBAL HEALTH SECTOR STRATEGY ON VIRAL HEPATITIS 2016–2021. World health organization. 2018;.
- [3]. Petruzzuello A. Global epidemiology of hepatitis C virus infection: An up-date of the distribution and circulation of hepatitis C virus genotypes. 2018;22(34).
- [4]. Hepatitis C virus: Virology, diagnosis and treatment. [Internet]. 2018 [cited 31 October 2018];7(10): 1377–1389. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4450201/>
- [5]. Jawetz E, Brooks G, Melnick J, Adelberg E, Carroll K, Hobden J et al. Jawetz, Melnick, & Adelberg's medical microbiology. New York: McGraw-Hill Medical; 2016.
- [6]. H. Patel et al. Department of Microbiology GMERS Medical College, Valsad, Gujarat, Study of Prevalence of Hepatitis C Virus (HCV) Infection in a Patients attending Tertiary Care Hospital Valsad, Gujarat, India, *International Journal of Current Microbiology and Applied Sciences*, ISSN: 2319-7706 Volume 6 Number 5 (2017) pp. 2783-2787, Journal homepage: <http://www.ijcmas.com>.
- [7]. Bhattacharya S et al. Department of Microbiology, Jawaharlal Institute of Postgraduate Medical Education and Research, Pondicherry, India, *Indian Journal of Medical Microbiology* Year: 2003 | Volume : 21 | Issue : 1 | Page : 43–45, Seroprevalence of hepatitis C virus in a Hospital based general population in South India.
- [8]. Chakravarti A, Verma V. Prevalence of hepatitis C and B viral markers in patients with chronic liver disease: A study from Northern India. *Indian Journal of Medical Microbiology*. 2005;23(4):273--274.
- [9]. Maity S, Nandi S, Biswas S, Sadhukhan SK, Saha MK. Performance and diagnostic usefulness of commercially available enzyme linked immunosorbent assay and rapid kits for detection of HIV, HBV and HCV in India. *Virology journal*, 2012 Nov. 26; 9 (1): 1.
- [10]. Desbois D, Vaghefi P, Savary J, Dussaix E, Roque-Afonso AM. Sensitivity of a rapid immuno-chromatographic test for hepatitis C antibodies detection. *Journal of Clinical Virology*, 2008 Feb. 29; 41 (2): 129-33.
- [11]. Khan JK, Lone DS, Hameed A, Munim R, Bhatti M, Khattak AA, Usman M, Nadeem MF, Satti HS, Munir M. Evaluation of the performance of two rapid immuno-chromatographic tests for detection of hepatitis B surface antigen and anti HCV antibodies using ELISA tested samples. *Annals of King Edward Medical University*, 2010; 16 (1 SI).
- [12]. Batool A, Khan MI, Bano KA. Efficacy of immunoassay chromatography test for hepatitis-C antibodies detection. *J Ayub Med Coll Abbottabad*, 2009; 21 (3): 38-9.
- [13]. Waqqar S, Ansari F, Muneer MA, Hanook S, Azhar H, Sheikh SH, Gul M. A potential loophole in early diagnosis of the hepatitis B and hepatitis C. *Biomed Lett*. 2015; 1 (1): 21-24.
- [14]. Erhabor O, Kwaifa IK, Bayawa AM, Isaac ZI, Dorcas I, Sani I. Comparison of ELISA and Rapid Screening Techniques for the Detection of HBsAg among Blood Donors in Usmanu Danfodiyo University Teaching Hospital Sokoto, North Western Nigeria. *Journal of Blood and Lymph*. 2014 Sep. 26; 2014.
- [15]. Hayder I, Ahmed W, Alam SE. Comparison of Different ICT Kits for HBsAg and Anti HCV Using Gold Standard ELISA. *Pakistan Journal of Medical Research*, 2013 Apr. 1; 52 (2): 72.
- [16]. Kwenti TE, Njoum R, Njunda LA, Kamga HL. Comparison of an Immunochromatographic Rapid Strip Test, ELISA and PCR in the Diagnosis of Hepatitis C in HIV Patients in Hospital Settings in Cameroon. *Clinical Medicine and Diagnostics*, 2011; 1 (1): 21-7.

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