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RESEARCH ARTICLE

COMPARISON BETWEEN RAPID IMMUNO-CHROMATOGRAPHIC DEVICE TEST AND ELISA IN DETECTION OF HBSAG AND ANTI-HCV ANTIBODIES

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ABSTRACT

Introduction: In case of diagnosis of infectious disease, discordant results may have serious consequences among the patients as it causes unnecessary mental stress and tension. For proper diagnosis of infection as well as disease management and prevention, identification of appropriate test kit is necessary.
Method: ELISA was used as gold standard for comparative evaluation. 300 samples for HBsAg and 100 samples for Anti HCV were selected and tested on Elisa and ICT kits using separate panel-sera for each. Dual infections with HBV and HCV, co-infection with HIV and repeat samples of same patient were excluded.
Results: In our study HBV specificity was 97%, PPV was 81%, the sensitivity was 78% and the NPV was 97%. For HCV specificity was 93%, PPV was 66%, sensitivity was 70% and NPV was 94%. Our results are significant (P value < 0.05). False positive were 2.34%, 6% for HBV and HCV, false negative were 2.67%, 5% for HBV and HCV respectively.
Conclusion: Rapid assays must be used with caution and it is also important to validate these rapid assays by testing them in a given population to assess the effectiveness of these assays in detecting the genotypes and subtypes of HBV and HCV circulating in the region before using these tests routinely in diagnostic laboratories. They should be recommended only in poor settings or remote areas.

INTRODUCTION

Hepatitis is a general term meaning inflammation of the liver and can be caused by a variety of causes, including different viruses; such as hepatitis A, B, C, D and E. Hepatitis B and hepatitis C both are serious and common infectious disease of the liver, affecting millions of people throughout the world. The virus is transmitted through contact with the blood or other body fluids of an infected person. Jawetz *et al* (2013)

An estimated 240 million people are chronically infected with hepatitis B and 150 million people infected with hepatitis C. Worldwide more than 780000 people die every year due to complications of hepatitis B and 500000 people die due to complication of hepatitis C. A significant number of those who are chronically infected will develop liver cirrhosis or liver cancer. Who fact sheet (2015)

So many methods are available to diagnose Hepatitis B surface antigen and anti HCV antibody like ELISA (Enzyme linked Immunosorbent Assay), EIA (Enzyme Immuno Assay) and PCR (Polymerase Chain Reaction). EIA and PCR are expensive and are used in well equipped laboratories. Conventional ELISA is most referred screening technique and possesses good accuracy. Ijaz *et al* (2012)

For a highly infectious virus like HBV and HCV which causes a long term silent infection, accurate detection of the viral marker is essential for controlling the transmission of the virus. For this reason, it is necessary to validate detection methods prior to allowing their use in diagnostic laboratories. In many developing countries, ICA based rapid diagnostic tests are widely used to detect HBsAg and anti-HCV antibody for both diagnosis and screening of acute and chronic infections, although ideally, screening should be done using more advanced and accurate methods such as EIA, PCR or ELISA. Negative samples from patients referred for screening assays (rapid assays) are seldom re-tested, considering the costs of re-testing in resource poor settings. Hence, choosing a test with high sensitivity and NPV is more important than choosing a test with high specificity and PPV for routine use.

Although rapid tests are widely used in India, studies on accuracy indices of ICAs in the country are scarce. It is not safe

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to depend on the studies that have been performed in other countries because genetic diversities in HBV and HCV can result in differences in accuracy indices. Hence, the current study was planned to compare ELISA and rapid ICA based tests that have been used widely in India for detection of HBsAg and Anti HCV antibody. Due to their easy use and cheaper cost, the rapid tests are being used practically at all primary and most secondary health care facilities in India.

METHOD

ELISA was used as gold standard for comparative evaluation. 300 samples for HBsAg and 100 samples for Anti HCV were selected and tested on Elisa and ICT kits using separate panel-sera for each. The sample size was calculated by the prevalence published in a previous study conducted in Mewat, (5.6% for HBsAg and 0.68% for HCV) (97% confidence limit). Prakriti *et al* (2015) Dual infections with HBV and HCV, co-infection with HIV and repeat samples of same patient were excluded. For ELISA ErbaLIsa Hepatitis B by Transasia Bio- Medicals Ltd and Hepa Scan HCV ELISA by Bhat Bio-Tech India (P) Ltd for detection of HbsAg and anti-HCV antibodies. Rapid card tests used were Meriscreen HBsAg manufactured by Meril Diagnostic Pvt. Ltd, Virucheck Anti HCV manufactured by Orchid Biomedical System. We followed their particular standard protocol to run the tests.

Cost-effectiveness analysis

For cost effective analysis cost of ICT kits/device and their sensitivity was compared using ELISA as Gold standard and by that comparison the most sensitive and cost effective kit was identified. Sensitivity of a test is defined as the ability to correctively identify the infected individual as also its ability to detect very small amount of analyte. Specificity as the ability to correctively identify the uninfected individual i.e. there should be no false positive. Negative Predictive Value (NPV) as the proportion of those with a negative test result who are uninfected and Positive Predictive Value (PPV) as the proportion of those with a positive test result who are actually infected.

Accuracy or Efficiency is the ability of test to correctly identify all positive as positive and all negative as negative. Likelihood ratio for positive result (LR+) and likelihood ratio for negative result (LR-) also calculated.

The sensitivity, specificity, Accuracy, negative predictive value and positive predictive value of rapid test were calculated in comparison to ELISA. All values expressed as percentage. Sensitivity was calculated as true positive/(true positive + false negative) x100; specificity as true negative/(true negative + false positive)x100 NPV as true negative/(true negative + false negative)x100 PPV as true positive/(true positive + false positive)x100; Accuracy as true positive +true negative/true positive + false negative + true negative + false positive; LR+ for positive result as sensitivity/100-specificity; LR- for negative results as 100-sensitivity/specificity. Torane *et al* (2008)

RESULTS AND DISCUSSION

300 (ELISA confirmed) samples for HBsAg and 100 (ELISA confirmed) samples for Anti HCV were selected and tested on ICT kits. Out of 300 samples 30 was positive and 270 was negative in ELISA. We further tested same sample with Rapid test without knowing the result of ELISA for particular sample. Similarly 100 samples were tested for HCV out of which 12 were ELISA positive and 88 were negative. The results of ICT kits on the basis of sensitivity and specificity were compared for HBsAg and Anti HCV and are depicted in Table-1 & 2.

For HBV specificity was 97.47% and the PPV was 81.08%. However, the sensitivity was 78.94% and the NPV was 97.12%. Raj *et al* reported, sensitivity was 79% and specificity was 98.9% Raj *et al* (2001). Another study showed 100% sensitivity of ICT method with a specificity of 91.7% and 99.2% for HBsAg and HCV respectively. Zahoorullah *et al* (2001). Khan *et al*. (2010) found sensitivity 53% (HBsAg) and 50% (HCV) although the specificity was 100% and 95% respectively. Kaur *et al* 2000 reported 100% specific and sensitivity was HCV 87.5% HBV 93.4% use ELISA to pick up all false negative.

In contrast to our study some studies have observed ICAs to have high sensitivity and specificity. A study reported by Ansari *et al* (2007) showed that rapid assays with strip or device had sensitivity between 97.5% to 99.2% and specificity between 97.5% and 99.2%. In a different study using two ICAs, the sensitivity and specificity were 100%.Sato *et al* (1996). Lin *et al* (2008) demonstrated an overall specificity of 98.7% and its sensitivity was almost 100%.

Table No. 1 Evaluation of rapid HBsAg kits with ELISA

	ELISA positive	ELISA negative	Total	Sensitivity	Specificity	PPV	NPV	Acc	LR+	LR-	P value
Rapid reactive	22	7	29 (9.6%)								
Rapid non reactive	8	263	271 (90.4%)	78.94%	97.47%	81.08%	97.12%	95.23%	31.20	0.012	<0.05
Total	30 (10%)	270 (90%)	300								

PPV; positive predictive value, NPV; negative predictive value, Acc; accuracy, LR+ likelihood Ratio for positive result LR- Likelihood Ratio for negative result

Table No.2 Evaluation of rapid anti HCV kits with ELISA

	Elisa positive	Elisa Negative	Total	Sensitivity	Specificity	PPV	NPV	Acc	LR+	LR-	P value
Rapid reactive	7	6	13 (13%)								
Rapid non reactive	5	82	87 (87%)	70.58%	93.61%	66.66%	94.62%	90.09%	11.04	0.314	<0.05
Total	12 (12%)	88 (88%)	100								

PPV; positive predictive value, NPV; negative predictive value, Acc; accuracy LR+ likelihood Ratio for positive result LR- Likelihood Ratio for negative result

A study from India Kaur *et al*. (2000) has observed that ICAs has a specificity of 100% but the sensitivity was 93.4%. Study from Seoul showed 97% sensitivity and 100% specificity for detecting HBsAg. Irwig *et al* (2002). In another study in healthy individuals from Karachi showed comparable sensitivity and specificity of ICT kits with ELISA technique Qasmi *et al* (2000).

For HCV specificity was 93.61% and PPV was 66.66% however sensitivity was 70.58% and NPV was 94.62%. P value was < 0.05 that is significant. In contrast to our study Maity *et al* (2012) revealed a higher PPV in rapid tests along with better efficiency (100%) than ELISA in most of the cases. Ijaz *et al* (2012) reported sensitivity 86-93%. Similar to our study Sridhar *et al* (2012) reported that the sensitivity of rapid immuno-chromatographic test kits used for anti-HCV antibodies screening was significantly low and the rapid tests are inferior compared to ELISA. Several evaluation studies have noted that the specificity and the PPV are high in ICAs but sensitivity and the NPV are less as observed in our study. Results of the current study indicated that both ICAs tested are less accurate when compared to the ELISA. Same results reported by many investigators. Hussain *et al* (2011), Clement *et al* (2002), Khan *et al* (2010).

Ideally rapid devices should have a high degree of sensitivity and a reasonable specificity to minimize false positive and false negative results. False positive in our study were 2.34%, 6% in HBV and HCV respectively. False Negative was 2.67% in HBV and 5% in HCV. False positivity is high in our study similar to Gul *et al* (2009). Although in many instances false positive results are preferable to false negative results when screening large groups, as positive serology triggers repeat testing with alternative method for case confirmations but false negative results may jeopardize human safety.

Different ICA based rapid assays used for HBsAg detection in the serum may not have the same accuracy index in every region since there can be differences in the prevalence of HBV infection in a given population. Most of these rapid assay use recombinant proteins from the prototype virus alone, specifically for HCV. Eleven type of genotype of HCV and eight type of genotype of HBV prevalent in different region of world. Moreover, the circulating subtype/s and genotypes of HBV and HCV show varied geographical and epidemiological distribution. (WHO fact sheet 2015). In such cases ICA that does not cover this particular subtype/s will not detect this type when testing. This may be the reason why one serum sample that was non-reactive for one step test was reactive using the ELISA. Purdy *et al* (2006).

Further work is needed as data on the circulating genotypes and mutants of HBV and HCV are widely available in India. Failure of rapid test kit to detect HBV and HCV reactive samples may be due to inadequate coating of the antigen, different nature of antigen used and genetic heterogeneity of the virus prevalent in that area. Torane *et al* (2007).

Rapid assays must be used with caution and it is also important to validate these rapid assays by testing them in a given population to assess the effectiveness of these assays in detecting the genotypes and subtypes of HBV and HCV circulating in the region before using these tests routinely in diagnostic laboratories. There are no approved rapid assays by the food and drug administration (FDA) and CE mark for European Union for HBsAg and HCV detection although several rapid tests for screening for HIV have been approved. Lin *et al* (2008)

In conclusion we reported rapid test are less efficient than ELISA. They should be recommended only in poor settings, remote areas and peripheral health facilities. HBV and HCV are highly dangerous infection for community; false negative results leave a threat of silent transmission and spreading of diseases among people and also create an urge for more sensitive assays like ELISA.

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