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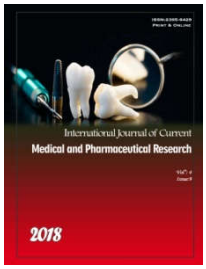

A STUDY TO DETECT HEPATITIS B AND HEPATITIS C INFECTION BY USING RAPID IMMUNO CHROMATOGRAPHIC TEST AND ELISA

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ABSTRACT

Introduction: Hepatitis B (HBV) and Hepatitis C (HCV) are serious global health problems affecting millions of people around the globe. About 1.5 million people die every year from HBV and HCV related chronic liver diseases such as end stage cirrhosis and Hepatocellular carcinoma (HCC) worldwide[2]. **Material and Methods:** Present Hospital based prospective study was conducted in the Department of microbiology K. D. Medical College Hospital and Research Centre. Duration of the present study was 6 months (September 2017 to March 2018). 100 serum samples for HBsAg and 100 serum sample for Anti HCV were included in this study. **Results:** for HBV, specificity was 96.7% and the Positive Predictive value (PPV) was 70%. However, the sensitivity was 77.8% and the Negative Predictive value (NPV) was 97.7% and for HCV, specificity was 93.1% and the Positive Predictive value(PPV) was 57.1%. However, the sensitivity was 61.6% and the Negative Predictive value (NPV) was 94.2%. **Conclusion:** In our study we concluded that Immuno Chromatographic Assay is less efficient than ELISA. No specific treatment and long term serious complications of HBV and HCV are highly dangerous for community; missing a positive case leave a threat of silent transmission and spreading of diseases among people and also create an urge for more sensitive assays like ELISA. Use of Immuno Chromatographic Assay should be recommended only in poor settings, remote areas and peripheral health facilities.

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INTRODUCTION

Hepatitis is a general term, defined as inflammation of the liver and can be caused by a variety of aetiology, including different viruses; such as hepatitis A, B, C, D and E. Hepatitis B and hepatitis C both are serious and common infectious diseases of the liver, affecting millions of people around the globe. Both Hepatitis B and Hepatitis C virus canbe transmitted through contact with the blood or other body fluids of an infected person[1].

An estimated 240 million people are chronically infected with hepatitis B and 150 million people infected with HCV (1, 2). Worldwide more than 780000 people die every year due to complications of hepatitis B and 500000 people die due to complications of hepatitis C. A significant number of those who are chronically infected will develop end stage liver cirrhosis or Hepatocellular carcinoma (HCC)[2].

There are so many methods available for diagnosis of Hepatitis B and Hepatitis C. Hepatitis B can be detected by HbsAg rapid kits, ELISA (Enzyme linked Immunosorbent Assay), EIA (Enzyme Immuno Assay) and PCR (Polymerase Chain Reaction). Hepatitis can be detected by rapid Immuno Chromatographic assay, ELISA (Enzyme Immunosorbent Assay) and PCR (Polymerase Chain Reaction). Both EIA and PCR are costly and require well-equipped laboratories. Conventional ELISA is most preferred screening technique and possesses good sensitivity and specificity.

HBV and HCV causes a long term silent infection, so for such highly infectious diseases, accurate detection of the viral marker is essential for controlling the transmission. For this, it is extremely important to validate detection methods prior to their use in diagnostic laboratories. Ideally screening should be done by more sensitive and specific methods such as ELISA but due to easy use and cheaper cost, Immuno Chromatographic Assay(ICA) based rapid tests are widely used to detect HBsAg and anti-HCV antibody for both diagnosis and screening of acute and chronic infections at all primary and most secondary health care centresin developing nations[3].

Although rapid tests are widely used in countries like India, studies on accuracy of ICAs are scarce. As genetic diversities in HBV and HCV can result in differences in accuracy indices, depending on the studies performed in other countries, it is not safe to use ICAs. Hence, the present study was planned to compare ELISA and rapid Immuno Chromatographic Assay (ICA) based tests that have been in use for detection of HBsAg and Anti HCV antibody.

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MATERIALS AND METHODS

Present Hospital based prospective study was conducted in Dept. of microbiology K. D. Medical College, hospital and Research Centre. Duration of present study was 6 months (September 2017 to March 2018). 100serum samples for detection of HBsAg and 100serum samples for Anti HCV were included after clearance from Institutional Ethical Committee. Samples were tested on ELISA and ICA kits using separate panel sera for each.

Inclusion criteria*:* All the patients from outpatient department and those who gave consent were included in this study.

Exclusion criteria*:* Dual infections with HBV and HCV, co-infection with HIV, who did not give consent and repeat samples of same patient were excluded. ELISA kit Hepa Alisa (J. Mitra) for Hepatitis B and Microlisa (J. Mitra) for HCV were used. Rapid card tests for HBV Hepacard HBsAg manufactured by Diagnostic Enterprise Pvt. Ltd was used. For HCV Tridot manufactured by Diagnostic Enterprise was used. We followed their particular standard protocol to run the tests. ELISA was used as gold standard for comparative evaluation. The sensitivity, specificity, Accuracy, negative predictive value and positive predictive value of rapid test were calculated in comparison to ELISA. All values were 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[4].

RESULTS

Out of 100 samples for detection of HBV, 9 were positive and 91 were negative by ELISA. When same samples were used for ICAs test, out of 100 samples 10 were reactive by ICAs and 90 were non-reactive. Similarly 100 samples were tested for HCV out of which 13 were ELISA positive and 87 were negative. The results of ICA test for HCV were 14 reactive and 86 non-reactive. Results of ICAs test on the basis of sensitivity and specificity were compared for HBsAg and Anti HCV and are depicted in Table-1 & 2.

DISCUSSION AND CONCLUSION

In the present study, results of Immuno Chromatographic Assay was compared with the ELISA for the screening of hepatitis B virus and Hepatitis C virus infections. In our study for HBV, specificity was 96.7% and the PPV was 70%.However, the sensitivity was 77.8% and the NPV was 97.7% and for HCV, specificity was 93.1% and the PPV was 57.1%.However, the sensitivity was 61.6% and the NPV was 94.2%. In a study, HBV specificity was 97% and sensitivity was 78% [5]. In a study done by Raj *et al*, sensitivity was 79% and specificity was 98.9%[6]. Another study showed 100% sensitivity of ICA method with a specificity of 91.7% and 99.2% for HBsAg and HCV respectively [7].In another study they found sensitivity 53% (HBsAg) and 50% (HCV) even though the specificity was 100% and 95% respectively. Same study reported 100% specificity and sensitivity for HCV was 87.5%, HBV 93.4% by using ELISA to pick up all false negative [8]. In contrast to our study some studies observed that Immuno Chromatographic Assay have high sensitivity and specificity. A study showed that rapid assays with strip or device had sensitivity between 97.5% to 99.2% and specificity between 97.5% and 99.2%[9].

In a study, Irwing *et al* demonstrated an overall specificity of 98.7% and its sensitivity was almost 100%[10]. In another study by Qasmi *et al*, reported that in healthy individuals from Karachi showed comparable sensitivity and specificity of ICA kits with ELISA technique, For HCV specificity was 93.61% however sensitivity was 70.58% and [11]. Another study revealed a higher PPV in rapid tests along with better efficiency (100%) than ELISA in most of the cases[12]. 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 as compared to ELISA[13], whereas Ijaz*et al*(2012) reported sensitivity 86-93%. Several studies have observed that the specificity and the PPV are high in Immuno Chromatographic Assay but sensitivity and the NPV are less which is similar to our study [14].Results of our study indicated that both Immuno Chromatographic Assays tested are less accurate when compared to the ELISA. Same results were reported by many other investigators in their studies[15, 16, and 17].

Table No. 1 Comparison of rapid HBsAg tests (ICA) with Gold standard ELISA for detection of HBV

ICA kits	Elisa positive	Elisa negative	Total	Sensitivity	Specificity	PPV	NPV	Acc	LR +	LR -
Reactive	7	3	10 (10%)							
Non-reactive	2	88	90 (90%)	77.8%	96.7%	70%	97.8 %	95%	23.59	.23
Total	9 (9%)	91 (91%)	100							

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 Comparison of rapid HCV tests(ICA) withGold standard ELISA for detection of HCV

ICA kits	Elisa positive	Elisa negative	Total	Sensitivity	Specificity	PPV	NPV	Acc	LR +	LR -
Reactive	8	6	14 (14%)							
Non-reactive	5	81	86 (86%)	61.6%	93.1%	57.1%	94.2%	89%	8.92	.41
Total	13 (13%)	87 (87%)	100							

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

Ideally rapid devices should have a high degree of sensitivity and a reasonable specificity to minimize false positive and false negative results. Although false positive results are preferable to false negative results when screening a large group, as positive serology triggers repeat testing with alternative method for case confirmations but false negative results may jeopardize human safety. False positive in our study were 3% and 6% in HBV and HCV respectively. False Negative was 2% in HBV and 5% in HCV. False positivity is high in our study similar to Gul*et al* (2009) [18].As there can be differences in the prevalence of HBV infection in a given population, different ICA based rapid assays used for HBsAg detection in the serum may not have the same accuracy index in every region. Eleven type of genotype of HCV and eight type of genotype of HBV prevalent in different region of world but most of these ICAs use recombinant proteins from the prototype virus alone, specifically for HCV. Moreover, the circulating subtype/s and genotypes of HBV and HCV show varied geographical and epidemiological distribution [2]. In such cases Immuno Chromatographic Assays that does not cover this particular subtype/s will not detect this subtypes when testing. This may be the reason why one serum sample that was non-reactive for one rapid test was reactive using the ELISA [19].Other reasons for 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[4].

Rapid assays must be used with caution and as data on the circulating genotypes and mutants of HBV and HCV are widely available in India, it is 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. Several rapid tests for screening HIV have been approved byfood and drug administration (FDA) and CE mark for European Union, but neither FDA nor CE have approved any specific rapid assays for the detection of HBsAg and HCV[20].

In our study we concluded that Immuno Chromatographic Assays are less efficient than ELISA. No specific treatment and long term serious complications of HBV and HCV are highly dangerous for community; missing a positive case leave a threat of silent transmission and spreading of diseases among people and also create an urge for more sensitive assays like ELISA. Use of Immuno Chromatographic Assay should be recommended only in poor settings, remote areas and peripheral health facilities.

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