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COMPARISON BETWEEN ELISA AND RAPID DIAGNOSTIC TEST FOR HEPATITIS B VIRUS SURFACE ANTIGEN TESTING

Microbiology

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ABSTRACT

INTRODUCTION: Hepatitis B Virus (HBV) infections are a global public health problem. India falls in the intermediate endemicity zone with prevalence of 2–7%, with an average of 4%. Timely diagnosis of Hepatitis B provides individuals an opportunity for intervention and to reduce transmission.

AIM: To compare sensitivity and specificity of rapid diagnostic test with ELISA.

MATERIAL AND METHODS: A study was conducted in the Department of Microbiology at Dr Ram Manohar Lohia Hospital from January 2018 to June 2018. Blood samples were tested for HBsAg by ELISA and positive and negative samples were also tested with rapid diagnostic test.

RESULTS: In our study 13964 blood samples were tested for HBV using ELISA. Sensitivity and specificity of the rapid card test was found to be 80.15% and 100%respectively.

DISCUSSION: Rapid diagnostic test can be used during emergency or odd hours, but their results must be followed by ELISA test results in a tertiary care hospital. Care must be taken to minimise false negative result to avoid silent transmission of infection.

KEYWORDS

Hepatitis B virus, ELISA

INTRODUCTION

Viral hepatitis is a systemic disease primarily involving the liver caused by Hepatitis Viruses A, B, C, D andE. Most of the cases of acute viral hepatitis are caused by Hepatitis A Virus (HAV) and Hepatitis E Virus (HEV) while both Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) are the leading causes of chronic hepatitis, cirrhosis and hepatocellular carcinoma[1].HBV infection is a global public health problem with more than 2 billion people affected worldwide[2].

HBV has a double stranded DNA encoding for P, X, core and surface proteins. The complex antigen found on the surface of HBV is called Hepatitis B surface antigen (HBsAg), which appears in serum 2–10 weeks after exposure to HBV and before the onset of symptoms or elevation of serum aminotransferase levels. In self-limiting acute HBV infection, HBsAg usually becomes undetectable after 4–6 months and if it persists for more than six months, it implies progression to chronic HBV infection. Consequently, HBsAg has been found to be a useful viral marker for both diagnosis of Acute HBV infection or Chronic HBV infection and in population screening[1,3,4]. India falls in the intermediate endemicity zone with prevalence of 2–7%, with an average of 4%[5].

Early identification of person with Chronic Hepatitis B enables them to receive the necessary care and treatment to prevent or delay progression of liver disease. In addition timely diagnosis of Hepatitis B provides individuals an opportunity for intervention and to reduce transmission. WHO has set a goal of Hepatitis elimination by 2030 and accordingly has set the target to identify 30% of persons living with HBV by 2020 and 90% by 2030, thereby WHO recommends that in areas with HBsAg seroprevalence between 2% to 5% all adults should have routine access to and should be offered HBsAg testing[6].

Various methods are available to detect HBsAg such as Immunochromatography(IC), ELISA (Enzyme Linked Immuno Sorbent Assay), Enzyme Immuno Assay (EIA),Polymerase chain reaction(PCR). Rapid diagnostic test based in IC is a rapid screening test for the qualitative detection of HBsAg in serum or plasma specimen. This test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HBsAg in serum or plasma. ELISA is an enzyme immunoassay technique for the detection of HBsAg in human serum or plasma[4].

According to WHO guidelines on Hepatitis B and C testing,settings where laboratory based testing services are available or accessible laboratory based immunoassay (ELISA) are recommended. While in settings where laboratory based testing services are not available or inaccessible, rapid diagnostic test based on IC which are easily available, cheaper, have rapid turnaround time and technically less demanding can be carried out for appropriate patient care and management[6].

In our hospital which is a tertiary care hospital, all antenatal cases and individuals who need surgical intervention are screened for HBsAg in routine as well as in emergency hours. As per WHO recommendation, in areas with seroprevalence of >0.4% single assay is recommended for diagnosis of chronic HBV infection[6].Thus this study was conducted with the aim to compare sensitivity and specificity of the rapid diagnostic test with ELISA.

MATERIALS AND METHODS

A study was conducted in the Department of Microbiology at Dr Ram Manohar Lohia Hospital and Post Graduate Institute of Medical Education and Research from January 2018 to June 2018.Blood samples of patients suspected for screening of hepatitis were received from various departments of our hospital in the plain vial for testing for HBV. Serum was separated and tested for HBsAg for HBV infection using ELISA. In our study ELISA was considered as the confirmatory serological assay. Sample tested positive by ELISA were also tested by rapid diagnostic test. Equal number (n=655) of ELISA negative samples were also randomly selected and tested by rapid diagnostic test. Results were analyzed.

RESULT

Of the 13964 blood samples tested for HBsAg by ELISA, 655 (4.69%) were found to be positive. On further testing of positive samples by rapid diagnostic test, of the 655 samples tested positive by ELISA, 130(19.85%) samples were found to be negative by rapid diagnostic test. Whereas 525 (80.15%) samples were found to be positive by both ELISA and rapid diagnostic test. Out of all the samples tested negative by ELISA, 655 of the samples were randomly selected and tested by rapid diagnostic test which were all found to be negative.

Using ELISA as confirmatory serological assay, sensitivity and specificity of the rapid diagnostic test was found to be 80.15% and 100% respectively. Positive predictive value and negative predictive value were determined to be 100% and 83.44% respectively.

DISCUSSION

In our study ELISA was taken as confirmatory serological assay for detection of HBsAg for HBVand the results of rapid diagnostic test were compared with it. HBsAg screening using rapid diagnostic tests showed sensitivity as 80.15%, specificity 100%, positive predictive value 100% and negative predictive value 83.44%.Farooqui et al[7] reported sensitivity of 78.94% and specificity of 97.47%, positive predictive value of 81.08% and negative predictive value of 97.12%.In another study Raj et al[8] reported sensitivity of 79% and specificity of98.9%. While Khan et al [9] found sensitivity and specificity to be 53% and 100% respectively.

In contrast to our study Mishra et al[4] reported the sensitivity of rapid card test to be 95.12% and specificity of 99.82%. Kaur et al[10]reported sensitivity of 93.4% and 100% specificity.International study done by Lin et al[11] reported sensitivity of 100% and specificity of 98.7%. Another study by Irwiget al[12] reported sensitivity and specificity of 97% and 100% respectively.

Different 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 genotypic prevalence of HBV infection in a given population. Most of these rapid assay use recombinant proteins from the prototype virus alone. Eight genotypes of HBV are prevalent in different regions of the world. Moreover, the circulating subtypes and genotypes shows varied geographical and epidemiological distribution. In such cases rapid assays that do not cover these particular subtypes will not detect the type when testing[4,7]. Analytic sensitivity and limit of detection of rapid diagnostic test have been reported to be low as compared to EIA[6]. Another reason for failure of rapid diagnostic test kit to detect reactive samples may be due to inadequate coating of the antigen or antibody and unfavourable storage conditions [4,7]These may be the reason why serum samples that were reactive using the ELISA were nonreactive for rapid diagnostic test[4,7].

ELISA is a laboratory based test that requires trained personnel, technical expertise and relatively takes longer time than rapid diagnostic test. For screening purposes rapid diagnostic tests are cheap, quicker, enable early detection at sites where laboratory facilities and trained manpower are not available. These rapid tests reduce the potential for loss of follow up of a case when results are not given straight away. Ideally rapid devices should have a high degree of sensitivity and a reasonable specificity so as to minimize false positive and false negative results. Although 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 miss potential source of infection[4,6,7.]

According to WHO ELISA sensitivity ranges from 74 to 100% and specificity ranges from 88% to 100%.There is a significant variation in performance between rapid diagnostic test brands and within the same brand with sensitivity ranging from50% to 100% and specificity ranging from69% to 100% [6]. Some assessment studies have indicated that Limit of Detection of ELISA was 50 to 100 fold better compared to rapid diagnostic test.

In our tertiary care hospital during emergency and odd hours when routine lab is closed, rapid diagnostic test results are reported, however later they are followed by ELISA test results.

CONCLUSION

Rapid diagnostic test for detection of HBsAg are readily available, cheap and easy to perform. However as compared to ELISA they are less sensitive (80.15%) and have low negative predictive value (83.4%). Rapid diagnostic test can be performed in emergency and odd hours however the results of rapid diagnostic test should be followed by ELISA test results, to minimise provision of false negative results.

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