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SHORT COMMUNICATION:

RAPID IMMUNOASSAY TECHNIQUE NOT SUFFICIENT FOR SCREENING OF PROSPECTIVE BLOOD DONORS FOR VIRAL HEPATITIS: A CASE STUDY IN OSUN STATE NIGERIA

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ABSTRACT:

Hepatitis B virus (HBV) is hyper endemic in Sub-Saharan Africa (SSA) and a major cause of chronic liver disease. Prior reports suggest a prevalence of 10.0% in the average risk Nigerian population. In Nigeria, investigators have found high HBV prevalence of 5.8% among voluntary blood donors. In the present study an evaluation of a rapid assay (RA) in comparison with Enzyme Linked Immunosorbent Assay (ELISA) for diagnosis of HBV infection among blood donors was investigated. A total of 183 blood donors were selected for this study, they were screened for HBsAg (Hepatitis B surface antigen) using a commercial rapid Clinotech Diagnostic and an ELISA HBsAg detection kit. Of the 183 serum samples 16.9% (31/183) were negative and 83.1% (152/183) were positive for the presence of HBsAg using ELISA. For Clinotech, 39.9% (73/183) were negative and 60.1% (110/183) were positive for the presence of HBsAg. The ELISA kit detected 23.0% (42/183) more positive serum samples compared to the Clinotech assay kit. An indication that the Clinotech assay kit was less sensitive than ELISA kit used in the present study, and that it should not be used alone for the screening of HBsAg.

Key words: Hepatitis B Virus, Diagnostic Kits, Blood donors, Sensitivity, Specificity, Nigeria

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INTRODUCTION:

Hepatitis B virus (HBV) is a major cause of liver disease morbidity and mortality worldwide, accounting for over 360 million cases of chronic hepatitis and 620,000 deaths per year [1]. It is hyper endemic in Sub-Sahara Africa (SSA) and a major cause of chronic liver disease [2]. Prior reports have suggested a prevalence of 10-15% in the average risk Nigerian population [1]. In Nigeria, high HBV prevalence of 5.8% among voluntary blood donors has been reported [3]. The common routes of transmission of HBV include perinatal, early in apparent childhood infection, tribal tattooing and scarification, sexual contact, blood transfusions, unsafe injection practices, injecting drug use and occupational exposure of health care workers [4]. HBV attacks the liver and can cause acute hepatitis and chronic disease such as chronic hepatitis B (CHB), cirrhosis and hepatocellular carcinoma (HCC).

Transmission to newborns from HBsAg positive mothers result in chronicity in over 90% of children while less than 10% of adults with acute HBV progress to chronic infection [4]. Most adult infected with HBV at early stage of their life may develop CHB without any symptoms, thus making the virus to be spread to others [5]. Therefore, to reduce the transmission and spread of HBV infection, accurate detection of HBV during blood transfusion is essential. Since HBsAg is the first marker to appear and become detectable within 4-12 weeks of acute infection; most diagnostic centres always use it for the screening of HBV infection [6]. When HBsAg persists for more than 6 months HBV become chronic, therefore, HBsAg is used as the viral marker for both diagnoses of acute and CHB infection. Rapid diagnostic tests (RDTs) which are considerably cheaper, faster and require no special training based on immunochromatography principles are widely used in Nigeria for the detection of HBsAg.

However, the problem is whether the immunochromatography assays (ICAs) can detect an acute HBV or CHB infection accurate enough since both have serious consequences in HBV infection control in Nigeria. Many studies have been performed to determine the accuracy indices of ICA based rapid tests on HBsAg detection. An important feature is that different ICAs have shown different accuracy levels, although these assays are based on the same principle [5]. It has been observed that ICA called Daina screen showed various sensitivity and specificity and therefore not reliable and should be backed up by other methods such as Enzyme Immunoassay (EIA) and Polymerase chain reaction (PCR) for detecting HBV infection since variant forms can be found in different countries [7,8]. Also, all ICAs do not possess equal sensitivity to detect all these HBV subgroups, which means some

products have less sensitivity to detect HBsAg from a certain HBV subtype [5]. It is unsafe to depend on the studies that have been performed in other countries because genetic diversities in HBV can result in differences in accuracy indices for detecting HBsAg for a given ICA based rapid test. In some recent studies in Nigeria, different rate of sensitivity, specificity, negative predictive value and positive predictive values of uncommon ICA kits for HBsAg detection in Ibadan and Calabar were found [9, 10]. Therefore, this study was conducted to compare the sensitivity and specificity of ELISA and the most common rapid ICA based techniques that have been widely used in Nigeria for serum HBsAg detection.

METHODOLOGY:

This cross-sectional study was carried out among blood donors at the Blood Transfusion Unit of Department of Hematology, Ladoke Akintola University of Technology Teaching Hospital (LTH), Osogbo, Nigeria. A total of 183 blood donors, consisting of 77.1% (141/183) males and 24.6% (45/183) females, age ranges between 18 and 56 years were enrolled in the study. These prospective blood donors were initially sorted using a structured questionnaire on risk behaviours and were physically examined by a clinician.

Ethical approval was sought from the ethical review committee of LTH, Osogbo, Nigeria and this was approved. Informed consent was obtained and form duly signed by each participant. Blood was collected by venipuncture and transferred into a labeled plain bottle.

The 183 blood samples collected were processed in the Haematology and Medical Microbiology Laboratories of the hospital. The 183 blood samples were screened for HBsAg using rapid Clinotech Diagnostic HBsAg detection kit (Horses Shoe Way Richmond B.C V7A 5H5, Canada) and Enzyme Linked Immunosorbent Assay kit (Bio Rad, UK). Analytical procedures were carried out according to the Manufacture's protocol.

The data were analyzed using Statistical Package for Social Sciences (SPSS version, 2016); p value less than 0.05 was considered to be statistically significant.

RESULTS:

Table 1 shows HBsAg detection using Clinotech and ELISA. Of the 183 blood samples tested with ELISA 16.9% (31/183) serum samples were negative and 83.1% (152/183) serum samples were positive for the presence of HBsAg. For Clinotech, 39.9% (73/183) were negative and 60.1% (110/183) positive for the presence of HBsAg.

The prevalence of HBV infection is higher among male participants 86.3% (158/183) than

females 13.7% (25/183). The number of HBV positive samples was higher with ELISA than Clinotech rapid kit. Positive predictive value (PPV), negative predictive value (NPV), sensitivity and specificity for HBsAg detection were calculated for Clinotech HBsAg Rapid test and ELISA (Table 2).

Table 1: HBsAg detection using Clinotech and ELISA

Assay for HBsAg detection	HBsAg Negative	HBsAg Positives
Clinotech	73 (39.9 %)	110 (60.1%)
ELISA	31 (16.9 %)	152 (83.1%)

Table 2: Accuracy indices of the Clinotech and ELISA

Accuracy indices	PPV (%)	NPV (%)	Sensitivity (%)	Specificity (%)
Clinotech	100.0	88.4	42.5	100.0
ELISA	100.0	100.0	100.0	100.0

DISCUSSION:

In Nigeria, ICA based rapid diagnostic kits are widely used to detect HBsAg for both diagnosis and screening of HBV infections, instead of advanced and accurate methods such as ELISA. Negative samples from patients referred for rapid assay are seldom re-tested, considering the costs of retesting in resource poor settings; hence, performing a test with high sensitivity and NPV is more important than choosing a test with high specificity and PPV for routine use [11, 12]. Results of this study indicated that Clinotech rapid kits are less accurate when compared to the ELISA. Specificity and PPV were 100% for Clinotech. However, the sensitivity and the NPV were less when compared to the 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. Khan *et al.* [8] reported specificity and PPV of 79% and 98.9% respectively. Similarly, Afolabi et al. have also posited that the sensitivity of most of the rapid test kits is not adequate when compared with EIA for early detection of HBV infections [9]. Different ICA based rapid assays used for HBsAg detection in the serum may not have the same accuracy

index in every region due to different prevalence and circulating subtypes of HBsAg in different locations. In such cases ICA that does not cover these subtypes will not be ideal for routine testing.

This may be the reason why serum samples that were non-reactive for Clinotech were reactive using the ELISA technique in our present study. Further work is needed as data on the circulating genotypes and mutants of HBV are not widely available in Nigeria. ICAs need regular validation with an accepted EIA for the detection of HBsAg if rapid ICAs are used for diagnostic and screening purposes in resource poor settings.

Rapid assays must be used with caution and it is also important to validate these rapid assays by testing them in each population to assess the effectiveness of these assays in detecting the genotypes and subtypes of HBV circulating in the region before using these tests routinely in diagnostic laboratories.

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