

Immunochromatographic Testing Method for Hepatitis B, C in Blood Donors

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Abstract

Background: Hepatitis is an inflammatory condition of the liver and viral hepatitis is a conventional term used to denote hepatitis caused by hepatotropic viruses (Hepatitis A-G). High prevalence of these viruses are reported in Nigeria. Hepatitis B and C may cause liver cirrhosis and they can be contacted through contaminated blood and blood products. Many blood banks in Nigeria screen for hepatitis B and C using immune-chromatographic screening method (Rapid test strip). This is because these strips are readily available in the market, cheap, requires no electricity for storage, special training or equipment before use. The intent of our study is to compare the sensitivity of this method using an advanced immunological method.

Method: 660 potential donors are tested for hepatitis B surface antigen (HBs Ag) and hepatitis C virus antibody using immune-chromatographic test strip and ELISA methods.

Result: We found out that 38 (5.7%) out of 660 subjects tested positive for HB_s Ag using immunochromatographic method while 71 (10.8%) were positive using ELISA. None is positive for hepatitis C antibody using immunochromatographic method while 4 (0.6%) subjects were positive using ELISA method.

Conclusion: Immunochromatographic method is not good enough to screen blood donors for hepatitis B and C.

Keywords: Immunochromatographic; ELISA; Hepatitis B; Hepatitis C; Blood donors

Introduction

Hepatitis is an inflammatory condition of the liver and its epidemiology varies among regions. Viral hepatitis is caused by hepatotropic viruses (Hepatitis A-G). According to the National Centres for Disease Control and Prevention, hepatitis A virus (HAV), hepatitis B virus (HBV) and hepatitis C virus (HCV) are the most common types worldwide. In Nigeria, viral hepatitis attracts lesser awareness compared to malaria, tuberculosis, and HIV/AIDS. Hepatitis B and C viruses are the major cause of acute and chronic hepatitis, liver cirrhosis and hepatocellular carcinoma [1-4]. Hepatitis B virus (HBV) is transmitted vertically (mother to child) [5,6], parenterally and sexually. Hepatitis C virus (HCV) is transmitted parenterally although there is a low rate of sexual and vertical transmission, which is more likely to occur in co- infections (HIV/HCV) [7,8]. Acute or chronic active HBV infection is indicated by the presence of HBs Ag in the serum or plasma [9], while the presence of hepatitis C antibody in the serum or plasma is an indication of HCV infection, although this does not indicate whether the infection is acute, chronic or resolved [10].

Nigeria is among the nations where large quantity of blood is used annually due to malaria, infections, road traffic accidents, and pre and post natal complications. Screening of HIV, Hepatitis B virus is a routine procedure in most Nigerian blood banks, but lately a few blood banks have include hepatitis C virus to this routine. Although confirmation of hepatitis B and C viral infection is based on advanced immunological, molecular and histological techniques⁹, the instruments and chemicals are relatively expensive considering the budget of an average private or government owned blood bank in Nigeria, for this reason, blood banks use immune-chromatographic test strips, to screen hepatitis B and C in blood donors. These rapid test strips are developed by different pharmaceutical and diagnostic companies and their brand varies from one country to the other. Their mode of action is based on common principle of antibody present in the test serum or plasma reacting with

the protein coated particle and migrating upward on a membrane chromatographically by capillary action to react with recombinant antigen present on the membrane thereby generating a colour line in the test region. These test strips are one step rapid test, cheap and fit into the budget of many of the Nigerian blood banks. They are also readily available in the market; require no electricity for storage or special training or equipment before use. The test strips manufactures also claim that these test strips have relatively high sensitivity, specificity and accuracy but there are reports querying these claims [9,11]. The trend in Nigeria blood bank is towards the use of these strips, but studies comparing strips method of blood screening with any advanced immunological or molecular method are very scarce. Therefore the intent of this study is to compare rapid test strip screening method with an advanced immunological method.

Methods

A total of 660 potential blood donors in 20 private blood banks in Sagamu, Remo Ogun state, Nigeria were enrolled for the study, an informed consent was obtained from individuals before their inclusion in this study.

3ml of venous blood was aseptically drawn from antecubital

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ASSAY TECHNIQUES AND % DISTRIBUTION

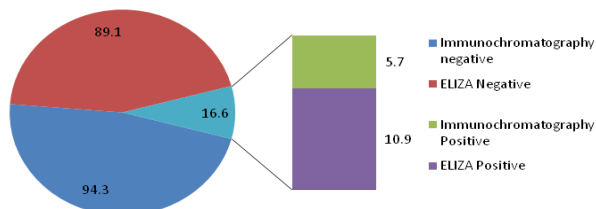


Figure 1: Comparison of Performance of Immunochromatographic and ELISA methods for HBsAg.

ASSAY TECHNIQUES AND % DISTRIBUTION OF HCV

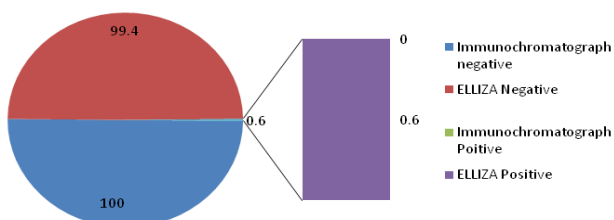


Figure 2: Comparison of Performance of Immunochromatographic and ELISA Methods for HCV.

vein of the participants into a plain bottle and was allowed to clot at room temperature; the blood was spun for 5 minutes at 2500 rpm in a bench centrifuge to obtain serum. The serum obtained was tested for HBsAg and HCV antibodies using Diaspot rapid diagnostic test strip bought from a reputable scientific dealer in Lagos, Nigeria, and a third generation ELISA kit produced by Human Gesellschaft fur Biochemical und Diagnostiscamb H, Germany. To perform these tests, the manufacturers' instructions were strictly followed. The data obtained is reported in simple percentage.

Results and Discussion

Viral hepatitis is among the major blood transfusion transmissible diseases. In blood banking, a false negative result may lead to transfusion of infected blood to an uninfected individual; this can be disastrous to the community, so a very sensitive method is required to detect the most hidden blood infection.

ELISA method detected more infected potential donors than the Immuno-chromatographic test strip, as shown in Figures 1 and 2. This indicates that rapid test strip as a sole diagnostic technique for the detection of hepatitis in blood donors, as is currently practiced in Nigerian hospitals is very hazardous to the blood recipients.

Diaspot was specifically chosen for this study because most of the laboratories in Nigeria, government hospitals, inclusive, all use this kit; because it is widely believed to be more sensitive and specific for the detection of HBsAg and HCV in the blood.

This study agrees with previous studies in other countries, which have stated that rapid test kits are not sensitive enough to be used solely for the detection of HBsAg and HCV in blood [9,11].

Conclusion

In this study, it is concluded that rapid test kits are not sensitive enough to confirm the hepatitis status of a donor in blood transfusion. Therefore, it is recommended that, rapid test kit should be used in conjunction with other immunoassay particularly Elisa technique. The essence of this study is to enlighten the poor resource countries that rapid test kits as a sole diagnostic tool for the detection of HBsAg and HCV in blood donors should be stopped.

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