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A Comparative study of Immunochromatographic test versus Chemoluminescence immunoassays immunoassay in hepatitis B surface antigen testing

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Abstract

Infection with Hepatitis B virus is a major public health problem worldwide where according to World Health Organization it affects over two billion people worldwide with 350 million of those suffering from chronic HBV infection and in Africa, there are 75 million people affected by the virus. In Rwanda the prevalence of HBV in the patients living with HIV is 4.3 $^{0/0}$ .While testing is obviously vital to timely case identification for a largely silent disease like HBV, accurate test for detection of the viral marker is essential for controlling the transmission of the virus and the availability of serological tests for HBV remains patchy in the Rwandan healthcare context. That is why we have done a comparative study in order to assess if the rapid tests would be accurate and able to detect an acute and chronic HBV infection in order to be used in all health facilities in Rwanda. The aim of this study was to compare the results from chemoluminescence immune assay (Architect HBsAg) versus immunochromatographic (SD BIOLINE HBsAg) assay for Hepatitis B surface antigen testing using ELISA as gold standard. This is cross section study which has been conducted at Rwanda National Reference Laboratory involving 200 samples collected from National Center for Blood Transfusion. These samples were submitted to hepatitis B surface antigen detection using three independent tests: SD BIOLINE HBsAg kit, Architect HBsAg Qualitative II ® and ELISA Kit Murex HBsAg. This study provides assurance that if the rapid tests are well used with follow up of procedures, it can provide reliable and accuracy results and they should be used on all patients suspected to have hepatitis B infection but the measures of quality control and quality assurance have to be taken into consideration.

1. Introduction

Viral hepatitis is a systemic disease that primarily affects the liver. Viral hepatitis is caused by hepatotrophic viruses (Hepatitis A-G) but hepatitis A, B and C account for a significant proportion of all cases of acute viral hepatitis (Khan JK *et al* 2010). Infection with Hepatitis B virus is a major public health problem worldwide where according to World Health Organization it affects over two billion people worldwide with 350 million of those suffering from chronic HBV infection and in Africa, there are 75 million people affected by the virus. In Rwanda the prevalence of HBV in the patients living with HIV is 4.3 $^{0/0}$ (RBC,2016) .While testing is obviously vital to timely case identification for a largely silent disease like HBV, accurate test for detection of the viral marker is essential for controlling the transmission of the virus and the availability of serological tests for HBV remains patchy in the Rwandan healthcare context. That is why we have that a comparative study in order to assess if the a rapid tests would be accurate and able to detect an acute and chronic HBV infection in order to be used in all health facilities in Rwanda. More than one million of infected die each year from complications related this infection, particularly cirrhosis, hepatic decompensation and hepatocellular carcinoma, making HBV the second major cause of cancer after smoking. (Antona 2007).

HBV infection is silent in those infected at an early stage of their life that is why most of people infected with hepatitis B remain unaware of their infection therefore frequently present with advanced disease and may transmit infection to others that is why accurate diagnosis of HBV infection by screening

suspected populations is necessary in order to control the exposed groups.

In addition testing and diagnosis of hepatitis B is the gateway for access to both prevention and treatment services, and it is a crucial component of an effective response to the hepatitis epidemic. Early identification of persons with chronic HBV infection enables them to receive the necessary care and treatment to prevent or delay progression of liver disease. Testing also provides an opportunity to link with people to interventions to reduce transmission, through counseling on risk behaviours and provision commodities, testing also precises the immune status thus incites to vaccinate unvaccinated persons at risk of exposure.

Hepatitis B surface antigen appears in serum 2 to 10 weeks after exposure to HBV and before the onset of symptoms or elevation of serum amino-transferase levels (Robert P, 2010). In self-limiting acute HBV infection, HBsAg usually becomes undetectable after four to six months. Persistence of HBsAg for more than six months implies progression to chronic HBV infections. Consequently, HBsAg has been found to be a useful viral marker for both population screening and diagnosis of acute HBV infection and chronic infection (Robert P, 2010)

There are several serological methods available to detect HBV makers including enzyme immunoassays (EIA), radioimmunoassays (RIA), immunochromatographic assays (ICA) and haemagglutination and chemoluminescence immunoassay (Candido, 2006).

Enzyme Linked Immunosorbent Assay is used at National Reference Laboratory and 13 District hospitals while chemiluminescent immunoassay is used in National Center for Blood transfusion to screen

However the availability of serological reagents for HBV remains patchy in the Rwanda healthcare context. Enzyme Linked Immunosorbent Assay (ELISA) reagents are available in some District hospitals and in National Reference Laboratory. There is also Chemoluminescence Immunoassay used to screen donated blood donors. Therefore it is imperative to look for a rapid tests which are accurate that could be now available to detect an acute and chronic HBV infection as it may be used in all health facilities in Rwanda in order to screen all suspected and to use at the community level, in particular, rural populations at the health center . It is in this context that we have done a comparative study of immunochromatographic test versus Chemoluminescence Immunoassay using ELISA as gold standard.

2. Methodology

This is cross section comparative study which was to compare the results from chemoluminescence immunoassay (Architect) and immunochromatographic (SDBIOLINE) technique for the period of one month. The samples have been tested on Architect in National Center for Blood Transfusion while rapids test and ELISA have been done in National Reference Laboratory. The samples have been collected from 200 patients who have been presented to National Center for Blood Transfusion for voluntary testing of hepatitis B in the period of one month from September to October 2010. The rules and protocols of safety at National Reference Laboratory lab and National Centre for Blood Transfusion have been respected when handling and selecting biological samples.

3. Results

Table I: Presentation of the results on SDBIOLINE HBS Ag test

The table I present the results of 200 samples tested on SDBIOLINE HBS Ag test

Technique / Result	SDBIOLINE HBS Ag test	
	Result	Percentage (%)
Positive	4	2
Negative	196	98
Total	200	100

This table I shows that from 200 samples analyzed on SDBIOLINE HBS Ag, 4 patients were positive representing 2 $^{0/0}$ while 196 patients were negative representing 98 $^{0/0}$.Those results are not far from the prevalence of HBV in whole population where according to the report of Rwanda Biomedical Center of 2015, the prevalence of HBV is 3 $^{0/0}$

Table II: Presentation of the results on Architect technique

The table II presents the results of 200 samples tested on Architect technique.

Technique / Results	Architect technique	
	Result	Percentage (%)
Positive	2	1
Negative	198	99
Total	200	100

The table II showed that from 200 samples analyzed on Architect, 2 patients representing 1 $^{0/0}$ were positive while 198 patients representing 99 $^{0/0}$ were negative. Those results are not far from the prevalence of HBV in whole population where according to the report of Rwanda Biomedical Center of 2015, the prevalence of HBV is 3 $^{0/0}$

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Table III: The results on Murex HBS Ag (ELISA)
The table III presents the results of 200 samples tested on Murex technique

Technique / Results	ELISA technique	
	Result	**Percentage (%)**
Positive	2	1
Negative	198	99
Total	200	100

The table III showed that from 200 samples analyzed on ELISA, 2 samples representing 1 $^{0/0}$ were positive while 198 samples representing 99 $^{0/0}$ were negative. Those results are not far from the results found on SD BIOLINE HBS Ag and that of Architect.

Table IV: Comparison of concordance between SD BIOLINE HBSAg and Architect techniques.
The table IV compares the result provided by SD Bioline and Architect tests of 200 samples. This comparison has been done on the hypothesis of the two tests to provide the same results

Results	Architect test	SD BIOLINE	Percentage of concordance	Percentage of discordance
Negative	198	196	98	2
Positive	2	4	98	2

The table IV showed that the concordance of results between Architect technique and SD BIOLINE equal to 98 $^{0/0}$ and the discordance of 2 $^{0/0}$.The discordance results observed have been tested using chi square to test if the discordance encountered is significance on the basic of hypothesis of two tests to give the same results. Then chi square has showed that there is not a significance difference to detect the HBV surface antigen between the SD BIOLINE and Architect where the chi square equal to 0,333 ; d.d.l = 1; P 0,O5.This means that the results provided by SD BIOLINE and Architect are the same and they can be used in hepatitis B surface antigen testing. Those results are similar to the results of the study conducted in Tanzania on the validation of the rapid test hepatitis surface antigens used in that country where they found that the concordance between SD BIOLINE and Architect equal to 99, 9 $^{0/0}$ (Candido, et *al.*, 2006).

Table V: Comparison of concordance between Architect and Murex techniques
The table V compares the result of 200 samples provided by Architect and that of Murex technique

Results	**Architect**	**Murex**	**Percentage of concordance**
Negative	198	198	100
Positive	2	2	100

The concordance of results between Architect technique and ELISA technique equal to 100 $^{0/0}$ and no discordance encountered between Murex and Architect. This means that the results provided by Architect are the same as those results provided by ELISA.This means that those tests have the same capacity to provide the accurate results. Also those results are similar of research conducted in Nigeria on the evaluation of the tests used in Blood transfusion donors where they realized that there is no difference between Architect HVB surface antigen and ELISA (Murex HVBS. (Ballesteros, 2013).

Table VI: Comparison of concordance between SD Bioline and ELISA techniques
The table VI compares the result provided by SD Bioline and ELISA (Murex) tests of 200 patients.

	SD BIOLINE	**Murex**	**Percentage of concordance**	**Percentage of discordance**
Negative	196	198	98	2
Positive	4	2	98	2

The table VI showed that the concordance of results between the Murex technique and SD BIOLINE technique equal to 98 $^{0/0}$ and the discordance of 2 $^{0/0}$.The discordance results observed have been tested using chi square to test if the discordance encountered is significant on the basis of hypothesis of two tests to provide the same results. Then chi square has showed that there is not a significance difference to detect the Hepatitis surface antigen between the Murex and SDBIOLINE where the chi square equal to 0, 333 d.d.l = 1; P > 0,O5 .This means that the results provided by rapid test are accurate and those rapid tests should be used in all health facilities in Rwanda. Those results are similar to the study conducted in India on the evaluation of the rapid test used in China where they found that he concordance between rapid test for surface antigen testing and ELISA equal to 99.9 $^{0/0}$.(*Young* 2014). This study provides assurance that if the rapid test is well used with follow up of procedures, it can provide reliable and accuracy results.

4. Conclusion

This study provides assurance that if the rapid tests are well used with follow up of procedures, it can provide reliable and accuracy results and they should be used on all patients suspected to have hepatitis B infection but the measures of quality control and quality assurance have to be taken into consideration.

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