LEVEL OF AGREEMENT OF THE HBsAg TEST IS EQUAL RAPID AND AUTOMATIC IMMUNOLOGY TEST METHOD IN SCREENING FOR HEPATITIS B VIRUS

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Objectives: The study aims to evaluate the level of consensus of HBsAg screening test using rapid test and automated immune testing methods in hepatitis B screening at Lao Cai Provincial General Hospital from May, 2024 to - June, 2024.

Methods: Cross-sectional descriptive study.

Results and conclusions: The study included 980 patients screened for HBsAg using rapid test and automatic immune testing from May, 2024 to June, 2024. The similarity between the two rapid and immunological test methods has Kappa = 0.92, almost complete agreement. The sensitivity of the rapid test is 98.9%, the specificity of the rapid test is 98.5% when considering the immunological method as the gold standard, the rate of HBsAg(+) screening results is > 70 COI screened by the method. Autoimmunity is 10.1%. The age group with the highest incidence is from (30 - 50 years old) accounting for 13%. The proportion of men is 11%, women is 8.5%, Patients residing in rural areas account for a higher rate of 12.2%, and 7.3% in urban areas with P < 0.05. The Tay ethnic group accounts for the highest proportion at 14.5%. There are 2.4% of HBsAg screening cases with indeterminate results (1 - 70 COI). The rate of HBsAg(+) carrier is 10.1%. The similarity between the two rapid and immunological test methods has Kappa = 0.92, almost complete agreement. The sensitivity of the rapid test is 98.9%, the specificity of the rapid test is 98.5%.

Keywords: Consensus, rapid test, immunity, HbsAg.

INTRODUCTION

Chronic hepatitis B virus (HBV) infection is a serious global health threat. According to the World Health Organization's report on the global hepatitis B infection situation in 2017, there are about 250 million people chronically infected with HBV, leading to nearly one million deaths every year. People with chronic HBV infection are at risk. progression to cirrhosis and hepatocellular carcinoma (HCC)[1]. According to the model to estimate the burden of disease caused by hepatitis B virus conducted by the Ministry of Health of Vietnam and the World Health Organization in 2017, it has been shown that an estimated 7.8 million people are infected with hepatitis B virus. Chronic is associated with serious complications such as cirrhosis and liver cell failure. HBV is one of the leading causes of chronic hepatitis and primary liver cancer in Vietnam, in which about 8 - 20% of people with chronic HBV progress to cirrhosis within 5 years[1]. According to Decision 1868/QD-BYT on promulgating guidelines for testing for hepatitis B and C viruses, the qualitative HBsAg test is used to screen and diagnose cases of HBV infection before signs of hepatitis appear. Currently applied HBsAg

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Date of Submissions: *June 24, 2024*
Date of reviewed completion: *June 05, 2024*
Accepted date for publication: *November 25, 2024*

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screening methods include rapid testing technique (RDT), enzyme-linked immunosorbent technique (ELISA), electrochemiluminescent immunoassay (ECLIA), chemiluminescent microparticle immunoassay (CMIA). Tests to monitor and evaluate treatment of hepatitis B are: AST and ALT test indexes, INR, total and direct bilirubin2. In Pham Van Hung's study on HBsAg detection rate, it showed that the ability to screen for HBsAg using the rapid test method is still limited. The rate of HBV infection screened by the rapid test is 2.7% and when testing negative samples of the rapid test for HBsAg, the positive detection rate increases by 0.43. Therefore, the group conducted research with the goal of consulting hospital leaders and the Biochemistry - Microbiology testing department on choosing appropriate methods to perform HBsAg screening and testing for patients coming for examination and treatment at the Lao Cai Provincial General Hospital.

SUBJECTS AND METHODS

Subjects: Evaluating the level of consensus of the HBsAg screening test: Patients are assigned to be screened for HBsAg using the automated HBsAg immunoassay method. The author performed the rapid HBsAg test method to evaluate the level of agreement between the two testing methods.

Exclusion criteria: Patients with unsatisfactory specimens with broken red blood cells, insufficient sample volume, incorrect samples or missing administrative information.

Methods: Cross-sectional descriptive study.

Data collection: Assess the level of consensus of the HBsAg screening test: Apply the convenient sampling method of plasma samples from patients coming for examination and screening for HBsAg at Lao Cai Provincial General Hospital from May - June, 2024. Data were entered using Excel software and analyzed using SPSS 20.0 software.

RESULTS

Table 1. Some general characteristics of study subjects with positive HBsAg rate

General features		HBsAg positive (N = 99)		HBsAg negative (N = 861)		p
		N	%	N	%	
Gender	Male	69	11	539	89	p = 0.224
	Female	30	8.5	322	91.5	
Age	18 - 30	17	8.8	177	91.2	p = 0.15
	> 30 - 50	50	13.0	336	87.0	
	> 50	32	8.4	348	91.6	
Residence	City	26	7.3	331	92.7	p = 0.01
	Countryside	73	12.2	530	87.8	
Ethnic groups	Kinh	44	8.6	469	91.4	p = 0.24
	H'mong	9	9.7	84	90.3	
	Tay	17	14.5	100	85.5	
	Dao	15	11.9	112	88.2	
	Other ethnic groups	14	12.7%	96	87.3%	

Comments: Some general characteristics of research subjects with positive HBsAg rate. The proportion of study subjects with HBsAg(+) in the male group was 11% and the female group was 8.5%. The difference in the rate of HBsAg(+) between men and women was not statistically significant with P > 0.05. The age group (30 - 50) has the highest rate of 13%. However, there was no statistically significant difference in the

rate between age groups and the HBsAg(+) group with P > 0.05. The distribution of patients in the rural group accounts for 12.2% of the difference in HBsAg(+) rate between the urban and rural groups, which is statistically significant with P < 0.05. The Tay ethnic group has the highest HBsAg(+) rate of 14.5%, the difference in HBsAg(+) rate between ethnic groups is not statistically significant with P > 0.05.

Table 2. Results of HBsAg screening by automated immunoassay

HBsAg autoimmunity	Quantity	Ratio (%)
Negative	861	87.5
Positive	99	10.1
Undefined	20	2,4
Total	980	100

Comments: The rate of negative research subjects by the automatic immune screening method was 87.5% and positive by the automatic immune method was 10.1%, with 2.4% of subjects not yet tested results can be determined.

Table 3. Some general characteristics of study subjects with positive HBsAg rate

Results of the auto-immune method	Automatic immunity		Quick test			
			Positive		Negative	
	Quantity	Ratio (%)	Quantity	Ratio (%)	Quantity	Ratio (%)
COI (1 - 70)	20	100	first	5	19	95
COI ≤ 0.9	861	100	14	1.6	847	98.4
COI > 70	99	100	98	99	first	first

Comments: There were 861 research subjects with immune results ≤ 0.9 COI when testing using the rapid test method, 14 cases had positive results, accounting for 1.6%, and 847 cases had negative results, accounting for 98,4%. The immune group had results of 1 - 70 COI, accounting for 20 cases whose results were not clearly determined by the immunological method, but when the results were performed by the rapid test method, 1 positive case accounted for 5% and 19 cases. negative accounts for 95%. The group of immune results > 70 COI by immunoassay method has 99 cases. After screening by rapid test, 98 positive cases accounted for 99% and 1 negative case accounted for 1%. Screening results by rapid test of 980 research subjects showed that there were 113 positive cases, accounting for 11.5% of the study subjects, and 867 negative cases, accounting for 88.5%.

Table 4. Evaluation of the level of agreement between the two methods based on the Kappa value

		Fast testing method	
		Negative	Positive
Autoimmune Method	Negative	849	13
	Positive	1	97
Kappa coefficient (K)		0.92	
Sensitivity of rapid test method		98.9	
Specificity of rapid test method		98.5	

Comments: After eliminating cases with unknown results, the remaining research sample to evaluate similarity is 960 samples. The kappa coefficient of 0.92 shows almost complete agreement when testing

for HBsAg screening using rapid test methods and automated immunoassay methods. Sensitivity and specificity of the rapid test method: When considering the immunological method as the gold standard, the sensitivity of the rapid test is 98.9% and the specificity is 98.5%.

DISCUSSIONS

Regarding characteristics of research subjects with HBsAg(+)

Of the 980 screening cases, 99 screening cases carried HBsAg(+), accounting for 10.1%. The rate of HBsAg carrying in our study is lower than that of the authors. Le Thi Diem Trinh In 20214 researched the infection rate of the Southern Kherme people, this rate was 10.4%, Pham Ngoc Thanh[5] when researching on people in the provinces of Dak Nong, Kom Tum, Gia Lai This rate is 11.4%. In our study, we did not find a statistically significant difference in the rate of HBsAg carrier between male and female groups with $p > 0.05$. This result is consistent with the research results of Pham Ngoc Thanh[5] $p = 0.75$. The age group with the highest proportion of HBsAg(+) carriers in our study is the 30 - 50 year old group (13%), consistent with Pham Ngoc Thanh[5]. The age group > 30 - 50 is often the age group in the prime working age group with extensive relationships and high sexual activity, making this age group account for a high proportion. The results of our study on the rate of HBsAg(+) carriers according to the place of residence found that there was a difference between urban and rural groups, this difference was statistically significant with $p < 0.05$. This result is consistent with the research of Le Thi Diem Trinh 20214. This rate is consistent with the population and housing census report of Lao Cai in 2022 when the proportion of people living in rural areas is 72.67%.

Evaluating the consensus level of HBsAg screening test using rapid test and automated immunoassay methods in hepatitis B screening

In our study, there were 20 cases of immunoassay with results 1 - < 70 (COI). According to the manufacturer, a result > 0.9 is considered a reactive sample. When using the rapid test method to screen these 20 samples, 1 sample had a positive result of 68.5 COI and the remaining 19 samples had negative results. Our research results are higher than the research of other authors when determining the value of the gray range for immunological methods such as Sarika Gail in 2018[6]. Results determined the gray range is 1 - 32 COI by comparison method is a quick testing method. Author Mohamed sahidi 2023[7] results determine the gray range is 1 - 52 COI comparison methods are ELISA and rapid test. According to Decision 26/QD-BYT on promulgating the document Guidance on technical procedures specialized in medical microbiology, it is recommended that cases of HBsAg screening results using the immunological method of 1 - > 70 COI automatically need to be performed by other methods[8]. When immunological screening results are indeterminate due to low HBsAg levels, HBsAg mutations, or drug therapy, a test should be performed to confirm the presence of HBsAg in serum or Plasma follows the principle of neutralizing specific antibodies[8].

Evaluate the level of similarity between the rapid test method and the automated immunoassay method in this study, after eliminating samples with unknown results, using the Kappa coefficient to determine the similarity of the results. Kappa result = 0.92, the level of agreement is almost complete, this result is also consistent with the studies of author Dipmala Das1 in 2018[9] with Kappa = 0.87, Sumiyo Okawaa in10 with Kappa = 0.9 when Compare the rapid test method and the automated immunoassay method. The research subjects of Dipmala Das1 in 2018[9] and our research are the same subjects of patients coming for examination and treatment at medical

facilities, however the author Sumiyo Okawaa10's is in the community. In some other studies, the results were not as consistent as ours, such as that of author Mohamed Sahidi[7] when considering ELISA as the gold standard to compare results of autoimmunity and ELISA with Kappa coefficient. was 0.39 mild agreement, when comparing the rapid test and ELISA groups showed Kappa 0.54 moderate agreement. Evaluation of the sensitivity and specificity of the rapid test when considering the immunoassay HBsAg screening results as the gold standard according to research by author Dipmala Das in 2018[9]. This author believes that the sensitivity and specificity of the test method faster than the immunological method when the sensitivity is 80%, the specificity is 100%, the results of author Dipmala Das[19] have lower sensitivity than our study and higher specificity than our study with sensitivity: 98.9%, specificity: 98.5%.

CONCLUSIONS

The rate of HBsAg(+) carrier was 10.1%. There were 2.4% of HBsAg screening cases with indeterminate results (1 - 70 COI). The similarity between the two rapid and immunological test methods had Kappa = 0.92, almost complete agreement. The sensitivity of the rapid test was 98.9%, the specificity of the rapid test was 98.5% when considering the immunological method as the gold standard.

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