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Serocomparison between Electrochemiluminescence Immunoassay and Enzyme-Linked Immunosorbent Assays for detection HBsAg and total HBcAb among blood donors at National Blood Transfusion and Research Center- Taiz Branch, Taiz, Yemen

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Abstract

Hepatitis B virus (HBV) is a small, circular, partial double stranded DNA virus classified under *hepadnaviridae*. Almost more than 350 million HBV infected persons were reported universally. Blood/its product transfusion represents one of the commonly routes of HBV transmission that may increase the HBV infection globally. HBV is diagnosed routinely by detection of both HBV specific antigens (HBsAg, HBcAg, HBeAg) and antibody markers (HBcAb). ELISA and Electrochemiluminescent immunoassay (ECLIA) are the most common methods to detect HBV antigens or antibodies. This study aimed to compare between ECLIA (Cobas e 411) and ELISA for detecting HBsAg and Total HBcAb among blood donors at National Blood Transfusion Center-Taiz branch (NBTRC-TB). 125 blood samples that were tested by ECLIA were chosen randomly and re-tested using ELISA method. The result of HBsAg seropositivity by ELISA method appeared as 28/125 (22.4%) compared to 25/125 (20%) by ECLIA method; whereas the result of total HBcAb seropositivity by ELISA method appeared as102/125(81.6%) compared to 100/125(80%) by ECLIA method. The current study appears to be a rapprochement between the results of two methods (ELISA and ECLIA) for detection HBsAg and HBcAb). In abscess of ECLIA, ELISA could be a good technique for blood screening before transfusion. Using molecular methods such as PCR will be more a curate to ensure blood safety before transfusion.

Keywords: HBsAg; HBcAb; ECLIA; Cobas e 411; ELISA

1. Introduction

Hepatitis B virus (HBV) is a small, circular, partial double stranded DNA *hepadnavirus* (1, 2). Mostly, there are more than 350 million persons infected with HBV universally (3-6).

HBV infection divides endemicity into three levels according to the World Health Organization (WHO). There are; high level more than 8%, intermediate 2 – 8%, and low level less than 2% (6, 7). Blood/its product transfusion is one route to increase HBV transmission and infection around the world (8, 9).

HBV is diagnosed routinely by measurement of both HBV specific antigens and antibody markers. HBsAg is the first marker used for HBV infection diagnosis, which is a serum protein present on the virion surface that is the first appearance antigen in a patient's serum during HBV infections. The next marker is HBeAg, which can appear after the production of HBsAg in a short time, indicating active virus replication. The third marker, HBcAg, is not used to detect HBV infection because it disappears from the patient's circulation in a short time, so they use HBcAb instead of it (10). The most common methods used to detect HBV antigens or antibodies in serum are ELISA and (ECLIA). ECLIA has been

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used for HBsAg screening in blood donors around the world and it is more sensitive than ELISA (11-13). ELISA is a solid stage type immunoassay where the antigens or antibodies present in a serum sample are specifically attached to them and then covalently bound with suitable second antibodies conjugated by enzymes that can catalyze the transformation of a substrate into a colored form (11). ECLIA (Cobas e 411) processes a highly reactive species are generated from stable precursors at the surface of an electrode. These highly reactive species react with one another, producing light. The development of ECL/Origen immunoassays is based on the use of ruthenium (I I)-tris(bipyridyl) [Ru(bpy)3]2+ complex and tripropylamine (TPA). The final chemiluminescent product is formed during the detection step. The chemiluminescent reactions that lead to the emission of light from the ruthenium complex are triggered electrically, rather than chemically. This is achieved by applying a voltage to the immunological complexes (including the ruthenium complex) that are attached to streptavidin-coated microbeads. The advantage of electrically initiating the chemiluminescent reaction is that the entire reaction can be precisely controlled (Roch, 2006). This study aimed to compare between ECLIA (Cobas e 411) and ELISA for detection of HBsAg and Total HBcAb by using samples that were found among blood donors at the National Blood Transfusion Center-Taiz branch (NBTRC-TB).

2. Material and Methods

The 125 samples were selected from blood donors attending NBTRC-TB. These samples were investigated for HBsAg and total HBcAb using Cobas e 411 method (Elecsys HBsAgII) REF 0468778190, (Elecsys Anti- HBc) REF (14). The 125 samples were divided into three groups. The number of blood donor samples in 3 groups was as the following: HBsAg Negative / HBcAb Positive = 75 samples, HBsAg Positive / HBcAb Positive = 25 samples and HBsAg Negative / HBc Negative = 25 samples. Samples that are HBsAg Positive / HBcAb Negative) are not available during collecting samples from blood donors because the rate of this group is very rare.

All samples were re-tested by using ELISA method and all results were compared by results of Cobas e 411 (ECLIA) method. Samples were tested for both HBsAg and HBcAb using ELISA kits according to manufacture protocol.

The HBsAg ELISA test was performed as follows; The sufficient number of wells were put in ELISA plate in suitable order. An amount of 50 µl of 2 positive controls, 3 negative controls and 125 samples were added into their respective wells. An amount of 50 µl of HRP-conjugated was added to each well except the blank. Plates were covered and incubated at 37 ^{0}C for 60 minutes. All the wells were washed 5 times. An amount of 50 µl of chromogen A and chromogen B solution was added into each well including blank and incubated at 37 ^{0}C for 15 minutes in a dark place. An amount of 50 µl of stop solution was added to each well with gently mixing. The result was read at 450 nm by the ELISA microplate reader. The absorbance was calculated and interpreted by using cut-off.

The HBcAb assay was performed as follows; The sufficient number of wells were put in ELISA plate in suitable order. An amount of 50 µl of 2 positive controls, 3 negative controls and 125 samples were added into their respective wells. An amount of 50 µl of working solution of conjugate was added to each well except the blank. Plates were covered and incubated at 37^{0}C for 60 minutes. All wells were washed 5 times. An amount of 100 µl of substrate mixture was added into each well including blank. Plates were incubated at 18 – 24 ^{0}C for 30 minutes in a dark place. An amount of 50 µl of stop solution was added into each well. The absorbance was read at 450 nm by the ELISA microplate reader. The result was calculated and interpreted using cut-off. Data of HBsAg and total HBcAb statistically analysed using the SPSS program (Version 26). The level of significance was taken as 0.05.

3. Result

In general, among 125 selected blood samples examined by the ECLIA method, the result of HBsAg seropositivity was 25/125 (20%); whereas, the seropositivity of HBcAb was 100/125 (80%). On the other hand, the 125 selected blood samples were re-examined to detect HBsAg and HBcAb by ELISA assay. Among these selected blood samples examined by ELISA, the seropositivity of HBsAg appeared in 28 (22.4%) of blood samples; whereas, most blood samples, 102 (81.6%) were seropositive for HBcAb (Table 1).

Through total 125 blood donor samples for detection both markers HBsAg and HBcAb. The result of HBsAg in the first group (HBsAg seronegative & HBcAb seropositive) was re-investigated by the ELISA method. The result appeared as 3/125 (2.4%) seropositive compared to ECLIA result 0/125 (0%). Whereas, the result of HBsAg seropositivity in the second group (HBsAg seropositive & HBcAb seropositive) appeared the same result 25/125 (20%) in two methods (ELISA and ECLIA). Also, in the third group (HBsAg seronegative & HBcAb seronegative), the HBsAg result appeared as the ELISA method, the same result as ECLIA method 0/125 (0%), as shown in Table (2).

Table 1 Comparative results of HBsAg & HBcAb detected by ECLIA & ELISA methods, among 125 blood donor samples

Method	Number of samples examined	HBsAg				HBcAb			
		Positive		Negative		Positive		Negative	
		No	%	No	%	No	%	No	%
ECLIA	125	25	20	100	80	100	80	25	20
ELISA	125	28	22.4	97	77.6	102	81.6	23	18.4

Table 2 Comparative result of HBsAg seropositivity in three groups of HBV by ECLIA **&** ELISA methods, among 125 blood donor samples.

HBV Groups	Number of Samples	HBsAg Seropositive by ECLIA		HBsAg Seropositive by ELISA		P-value
	No	No	%	No	%	
HBsAg seronegative & HBcAb seropositive	75	0	0	3	2.4	0.083
HBsAg seropositive & HBcAb seropositive	25	25	20	25	20	
HBsAg seronegative & HBcAb seronegative	25	0	0	0	0	
Total	125	25	20	28	22.4	

Statistically significant (P < 0.05).

Generally, the result of total HBsAg seropositivity detected by the ECLIA method was 25/125 (20%) compared to 28/125 (22.4%) by the ELISA method. The result of HBsAg showed no significant deference between the two methods, ELISA and ECLIA (p = 0.083) (Table 2). Regarding HBcAb seropositivity, 125 blood donor samples were retested by ELISA to detect HBcAb. The result of HBcAb in the first group (HBsAg seronegative & HBcAb seropositive) appeared as 73/125 (58.4%) seropositive compared to 75/125 (60%) which was detected by the ECLIA method. Whereas HBcAb detection appeared the same result by two methods (ELISA and ECLIA) in the second group (HBsAg seropositive & HBcAb seropositive), as 25/125 (20%). Finally, the HBcAb result by ELISA method in the third group (HBsAg seronegative & HBcAb seronegative) was shown as 4/125 (3.2%) seropositive compared to 0/125 (0%) by the ECLIA method. Generally, the result of total HBcAb seropositivity detected by the ECLIA method was 100/125(80%) compared to 102/125(81.6%) by the ELISA method. The result of HBcAb showed no significant deference between two methods, the ELISA and ECLIA (p = 0.416) (Table 3).

Table 3 Comparative result of HBcAb seropositivity in three groups of HBV by ECLIA & ELISA methods, among 125 blood donor samples.

HBV Groups	Number of Samples	HBcAb Seropositive by ECLIA		HBsAg Seropositive by ELISA		P-value
	No	No	%	No	%	
HBsAg seronegative & HBcAb seropositive	75	75	60	73	58.4	0.416
HBsAg seropositive & HBcAb seropositive	25	25	20	25	20	
HBsAg seronegative & HBcAb seronegative	25	0	0	4	3.2	
Total	125	100	80	102	81.6	

Statistically significant (P < 0.05).

4. Discussion

In the previous study, the comparison between results of ECLIA and ELISA for detection (HBsAg and HBcAb), it appeared that there is little discrepancy in detection the sensitivity between two methods which ECLIA is more sensitive than ELISA, whereas ELISA is more useful for investigation HBV seromarkers (13, 15).

ELISA methods have some advantages which include being easy for operation, less cost, and it is appropriate for using an open detection system (12). ELISA disadvantages involve time-consuming work, and experienced technicians (17).

In this study the comparison between results of ECLIA and ELISA for detection (HBsAg and HBcAb), showed the seropositivity rate in detection HBsAg by ELISA method was 22.4% while by ELCIA method was 20%. Similarly, the seropositivity rate in detection HBcAb by ELISA method was 81.6% while by ECLIA method was 80%. So, this study showed there was a little discrepancy and a rapprochement between results of ECLIA and ELISA for detection HBsAg and HBcAb.

In the previous study the comparison between results of ECLIA and ELISA for detection (HBsAg and HBcAb), appeared there is little discrepancy in detection the sensitivity between two methods which ECLIA is more sensitive than ELISA, whereas ELISA is more useful for investigation HBV seromarkers (13,15).

Despite the ECLIA and ELISA were appeared similar result for detection HBsAg and HBcAb, but the ECLIA method significantly more sensitivity and specificity than ELISA method (16).

5. Conclusion

This study showed no more different between results of two methods (ECLIA and ELISA), so that ELISA can be used instead of Cobas e 411 (ECLIA method).

Recommendation

Firstly, can be used ELISA method instead of Cobas e 411 (ECLIA) method (if not found) for investigation HBV in NBTCs and small blood bank in hospitals.

specificity method to enhance safety and at the same time reduce the blood units rejecting in our country.

Compliance with ethical standards

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Disclosure of conflict of interest

No conflict of interest to be disclosed.

Statement of ethical approval

The study was approved by the faculty of applied science at Taiz University (NO. 680). This study carried out among one hundred and twenty five selected randmly from 2129 blood donors at National Blood Transfusion and Research Center -Taiz Branch. One hundred and twenty five questionnaire were distributed. Permission for HBsAg and total HBcAb investigation by ELISA method was obtaind from Management of the National Blood Transfusion and Research Center -Taiz Branch and initial approval from the participants in the study.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

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