



Research Article

EVALUATION OF IMMUNOCHROMATOGRAPHIC ASSAY USED IN SCREENING OF HBsAg AMONG BLOOD DONORS IN A RURAL TEACHING HOSPITAL, SANGAREDDY

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ABSTRACT

Objectives: The present study was to assess ICT kit used in the screening process of HBsAg among blood donors in a rural teaching hospital, sangareddy.

Materials and Methods: In this study 1050 number of blood units were collected from donors containing both voluntary and replacement donors for a period of one year from January 2015 to December 2015. 1050 donors are tested for HBsAg by using ICT kit and ELISA method.

Results: We found 17 out of 1050 subjects tested positive for HBsAg by using ICT kit and ELISA.

Conclusion: The present study concludes that the overall performance of the rapid ICT kit for HBsAg was equally sensitive to ELISA and yet they were cheap and quicker. It can be recommended that ELISA comparable rapid devices may be allowed to be used for initial screening of hepatitis B especially, in remote areas or where cost is an issue.

Keywords: Hepatitis B surface antigen (HBsAg), Immunochromatographic test kit (ICT).

INTRODUCTION

Globally, Hepatitis B virus (HBV) infection is one of the major health problems. HBV infection mainly attacks the liver and can cause acute and chronic hepatitis, liver cirrhosis and liver cancer. According to World Health Organisation (WHO), about 240 million people are chronically infected with HBV. More than 7,80,000 deaths are occurring every year due to related complications of HBV, including liver cancer and liver cirrhosis [1,2].

Worldwide, the prevalence of HBV infection varies from one region to another. According to WHO, the HBV prevalence is classified into low endemicity (<2%), intermediate (2-7%)

and high endemicity (> 8%). High Prevalence of HBV is observed in East Asia and Sub-Saharan Africa (5-10%) and low prevalence of infection are observed in North America and Western Europe (<1%). In India, a prevalence of HBV is in the intermediate range (2-7%) [3,4]. The transmission of HBV infection mainly occurs through blood transfusion, parental transmission (mother to child) and sexual contact [5,6,7].

Every year millions of lives are saved due to the blood transfusion. According to WHO, safe blood is a universal right, which means blood that is fully screened and harmless to the recipient and is not contaminated with any blood

borne pathogenic diseases, such as HBV, HCV, and HIV. So, WHO made mandatory to screen pre-transfusion blood for all blood transfusion associated diseases. In India screening of each and every blood units are mandatory and it is routinely done in blood banks. So, for screening and confirmation of HBV infection is based on advanced molecular and immunological techniques. For these screening techniques they required well established lab, expensive instruments and well trained technicians. Which are relatively expensive, for this reason, blood banks are using rapid immunochromatographic test (ICT) kits, to screen HBV in blood donors [8,4].

The present study was to assess immunochromatographic test kits used in the screening of HBsAg among blood donors in a rural teaching hospital sangareddy.

METHODS AND MATERIALS:

The present study was conducted at the blood bank of MNR Medical Collage & Hospital, Sangareddy and Telangana State, India (Catering to rural population). In this study 1050 number of blood units were collected from donors containing both voluntary and replacement donors for a period of one year from January 2015 to December 2015. Blood donors were selected after taking detailed clinical history and brief medical examination. This study was approved by institutional ethical committee.

The fresh whole blood with a volume of 5ml was collected from each donor in a sterile blood collection tube pre-treated with EDTA. Serum was obtained after centrifugation. The Serological test was performed according to WHO recommendation, involving rapid diagnostics assays and ELISA.

All the serum samples were tested by Immunochromatographic test kits (Genomix One step Hepatitis B surface antigen test kit) and ELISA (Hepalisa, J. Mitra & Co. Pvt. Ltd, New Delhi, India) for HBsAg. The above investigations were carried out according to manufactures instructions.

Statistical analysis:

Performance of rapid ICT kits was evaluated in terms of sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and efficiency which can be defined as follows: Sensitivity = $[TP / (TP+FN)] \times 100$, Specificity = $[TN / (TN+FP)] \times 100$, Positive Predictive Value

(PPV) = $[TP / (TP+FP)] \times 100$, Negative Predictive Value (NPV) = $[TN / (TN+FN)] \times 100$, Efficiency = $[(TP+TN) / (TP+FN+TN+FP)] \times 100$.

RESULTS:

In the present study, out of total 1050 blood donors, 1018 (96.95%) were males and 32 (3.05%) were females. In our study, replacement donors were 785 (74.76%) and voluntary donors were 265 (25.24%) [Table1]. The recorded age range was 18- 50 years old and the age frequency distribution of infection is shown in table 2. Results show that seroprevalence of HBV infection 09 in the age group 21 – 30 years. Lowest prevalence was recorded in the 18-20 and 41- 50 age group. Out of 1050 samples, 17 were reactive; while the others were nonreactive for HBV as shown in table 3. Out of the 17 reactive samples, 12 were males and 05 were females are shown in table 2.

DISCUSSION:

Worldwide, blood transfusion became one of the major life-saving procedures in modern medicine. Though the blood transfusion saving the lives of many people there might be a major dis-advantage with blood transfusion was transmission of infections like Hepatitis B, Hepatitis C, and HIV. So, it is necessary to maintain safe blood transfusion procedures to prevent the transmission of deadly infectious diseases [4,9].

In the present study, the number of male donors 1018 (96.95%) were more than the number of female donors 32 (3.05%). Similar findings were observed by Rose et al. [10] and Singh K et al. [11]. The present study showing that majority of donors were replacement donors 785 (74.76%), while voluntary donors were 265 (25.24%). which is similar to the other studies done by Singh K et al. (84.43%) [11] and Arora D et al. (68.6%) [12], In India replacement donors constitute a major group of blood donors which is reflecting the lack of awareness in the general population [4]

Globally, detection and diagnosis of HBV infection are mainly based on immunological assays among which rapid ICT kit and ELISA are most common and widespread methods [13]. An important problem encountered at this point is the conflict between the results of two assays. This can be resolved depending on the availability of suitable kits. Generally, the sensitivity of the ELISA kits was good when compared to the rapid immunochromatographic test (ICT) kits. In terms of price, the cost of ELISA kit was very high

Table 1: Month-wise Distribution of Blood Donors according to Gender, Replacement and Voluntary donor.

| Month wise Distribution of Blood Donors according to Gender, Replacement and Voluntary donor. | | | | | |
|---|--------------------|---------------------|-------------------|------------------------|----------------------|
| Month wise | Total Donors (%) | Gender | | Donor Type | |
| | | Male Donors (%) | Female Donors (%) | Replacement donors (%) | Voluntary donors (%) |
| January | 80 (7.61%) | 78 | 02 | 52 | 26 |
| February | 103 (9.80%) | 97 | 06 | 66 | 31 |
| March | 97 (9.23%) | 96 | 01 | 59 | 37 |
| April | 107 (10.20%) | 103 | 04 | 70 | 33 |
| May | 96 (9.14%) | 94 | 02 | 71 | 23 |
| June | 76 (7.23%) | 74 | 02 | 62 | 12 |
| July | 65 (6.20%) | 63 | 02 | 53 | 10 |
| August | 95 (9.04%) | 92 | 03 | 84 | 08 |
| September | 79 (7.52%) | 76 | 03 | 66 | 10 |
| October | 81 (7.71%) | 79 | 02 | 60 | 19 |
| November | 101 (9.61%) | 99 | 02 | 82 | 17 |
| December | 70 (6.66%) | 67 | 03 | 60 | 07 |
| Total | 1050 (100%) | 1018(96.95%) | 32 (3.05%) | 785 (74.76%) | 265 (25.24%) |

Table 2: Distribution of blood donors with Hepatitis B infections according to age group

| Distribution of blood donors with Hepatitis B infections according to age group | | | |
|---|------------------------------|--------|-------|
| Age (years) | Hepatitis B (HBsAg) Reactive | | |
| | Male | Female | Total |
| 18-20 | 01 | 01 | 02 |
| 21-30 | 07 | 02 | 09 |
| 31-40 | 03 | 01 | 04 |
| 41-50 | 01 | 01 | 02 |
| Total | 12 | 05 | 17 |

Table 3: Evaluation of HBsAg rapid ICT kit with ELISA.

| Evaluation of HBsAg rapid ICT kit with ELISA | | | | | | | |
|--|---------------|----------|--------------|--------------------|--------------------|---------------------|---------------------|
| | Total samples | Reactive | Non-Reactive | True Positive (TP) | True Negative (TN) | False Positive (FP) | False Negative (FN) |
| Rapid ICT assay | 1050 | 17 | 1033 | 17 | 1033 | 00 | 00 |
| ELISA | 1050 | 17 | 1033 | 17 | 1033 | 00 | 00 |

Table 4: Comparison of parameters between rapid ICT and ELISA

| Comparison of parameters between rapid ICT and ELISA | | |
|--|-----------|-------|
| Parameters | Rapid ICT | ELISA |
| Sensitivity % | 100% | 100% |
| Specificity % | 100% | 100% |
| PPV | 100% | 100% |
| NPV | 100% | 100% |
| Efficiency | 100% | 100% |

whereas the cost of ICT kit for HBsAg detection was very cheap. The time taking for ELISA assay was more whereas by using ICT kits the screening of the specimens was done within 10 to 15 minutes only. So, because of this less expensive and easy to handle and rapid screening nature the rapid ICT test kits became an alternative for ELISA in blood banks ^[14]. Moreover now a day's majority of the ICT manufacturing companies are using synthetic antigens that help in increasing the specificity and sensitivity of the ICT Kits.

In the present study the rapid ICT kit was compared with the standard ELISA assay for screening of Hepatitis B infection. Results of the present study showed that the sensitivity and NPV of ICT kits used for HBsAg (Hepatitis B surface antigen) infection screening were significantly equal to the ELISA results. On the other hand, PPV and specificity of rapid ICT kits were equal to ELISA tests. Overall the efficiency for both rapid ICT kits and ELISA were equal, as shown in table 3&4. The results of this study were similar to the study done by Qasmi et al ^[15], Kaur H et al. ^[16] and Irwig L et al. ^[17].

CONCLUSION:

The present study concludes that the overall performance of the rapid ICT kit for HBsAg was equally sensitive to ELISA and yet they were cheap and quicker. It can be recommended that ELISA comparable rapid devices may be allowed to be used for initial screening of hepatitis B especially, in remote areas or where cost is an issue.

REFERENCES

- Lozano R, Naghavi M, Foreman K, Lim S, Shibuya K, Aboyans V, Abraham J, et al. Global and regional mortality from 235 causes of death for 20 age groups in 1990 and 2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet* 2012;380:2095-2128.
- Chaudary A. Epidemiology of Hepatitis B virus in India. *Hep B Annual*, 2004; 1:17-24.
- WHO core programme clusters. Family and community health. Hepatitis B. Community office for India. (<http://www.whoindia.org/en/selection6/section8.htm>)
- Nagababu Pyadala, Soumendra Nath Maity et al. Seroprevalence of Transfusion Transmissible Infections among Blood Donors attending in a Rural Teaching Hospital at Sangareddy. *Int J Biol Med Res.* 2015;6(4):5249-5253
- "Hepatitis B FAQs for the Public". Centers for Disease Control and Prevention. Retrieved 2015-08-24.
- Fairley CK, Read TR (February 2012). "Vaccination against sexually transmitted infections". *Current Opinion in Infectious Diseases* 25 (1): 66–72.
- Buddeberg F, Schimmer BB, Spahn DR (September 2008). "Transfusion-transmissible infections and transfusion-related immunomodulation". *Best Practice & Research. Clinical Anaesthesiology* 22 (3): 503–17.
- Guyton and Hall: Textbook of Medical physiology. 11th (ed). Page 640.
- Henderson AJW, Carswell F. Circadian rhythm of peak expiratory flow in asthmatic and normal children. *Thorax*. 1989; 44:410-414.
- Rose D, Sudharsanam A, Adankatti T, Babu PG, John TJ, et al. Increasing Prevalence of HIV antibody among blood donors monitored over 9 years in blood donors monitored over 9 years in blood banks. *Indian J Med Res.* 1998; 108:42–44.
- Singh K, Bhat S, Shastri S. Trend in Seroprevalence of Hepatitis B virus infection among blood donors of coastal Karnataka, India, *J Infect Dev Ctries* May 2009; 3(5):376-9.
- Arora D, Arora B, Khetarpal A, et al. Seroprevalence of HIV, HBV, HCV and syphilis in blood donors in Southern Haryana. *Indian J Pathol Microbiol.* 2010; 53:308-319.
- Khan JK, Lone DS, Hameed A, Munim MR, Bhatti M, Khattak AA, Usman M, Nadeem MF, Satti HS, Munir M: Evaluation of the performance of two rapid immunochromatographic tests for detection of hepatitis B surface antigen and anti HCV antibodies using ELISA tested samples. *Sp Ed Ann* 2010, 16:84–87.
- Khansari N, Mazhari SZ, Rezvan H: A comparative study of a rapid test and ELISA for the serological determination of HIV infection. *Acta Med Iran* 1993, 31:68–71.
- Qasmi SA, Aqeel S, Ahmed M, Alam SI, Ahmad A. Detection of Hepatitis B Viruses in Normal Individuals of Karachi. *J Coll Physicians Surg Pak* 2000; 10:467-9.
- Kaur H, Dhanao J, Oberoi A. Evaluation of rapid kits for detection of HIV, HBsAg and HCV infections. *Indian J Med Sci* 2000; 54: 432-4.
- Irwig L, Bossuyt P, Glasziou P, Gatsonis C, Lijmer J. Designing studies to ensure that estimates of test accuracy are transferable. *BMJ* 2002; 324: 669-71.