

Original Research Article

A study on effectiveness of rapid diagnostic test as compared to ELISA for HBsAg Detection at Blood Bank in Tertiary Care Hospital

Dr. Parth R. Goswami¹, Dr. Bhavin B. Padhariya²

¹Tutor, Government Medical College, Bhavnagar, Gujarat, India

²Assistant Professor, Government Medical College, Bhavnagar, Gujarat, India

***Corresponding author**

Dr. Parth R. Goswami

Email: goswamiparth42@gmail.com

Abstract: Hepatitis B virus is among common cause of transfusion transmitted disease. So it is necessary to diagnose HBsAg positivity before issuing blood to patient in blood bank. There are various methods for detection of HBsAg reactivity but our focus is to evaluate effectiveness of rapid diagnostic test kits as compared to ELISA methods at blood bank for screening of blood donors. This study was carried out at tertiary care hospital (blood bank), Gujrat , India from date of 01/01/2016 to 31/08/2016. We have tested total 10892 donor sample with using third generation ELISA kit as well as Rapid diagnostic kit. Rapid diagnostic kit showing sensitivity 87.5%, specificity 100 %, positive predictive value 100%, and negative predictive value 99.90%. Among all donor mean age group was 29 year and most of patients are male. Rapid diagnostic kits can be used in emergency situation as it is less time consuming and no specific training required but its sensitivity is less and gives false negative result in few donor so it cannot replace standard ELISA test.

Keywords: ELISA, Hepatitis B virus, Rapid diagnostic test.

INTRODUCTION

Hepatitis B is a potentially life threatening liver infection caused by the Hepatitis B virus and is the most serious type of viral hepatitis.

The Hepatitis B surface antigen (HBsAg) is the most frequently used to screen for presence of this infection. It is the first detectable viral antigen to appear. Individuals who remain HBsAg positive for six months are considered to be Hepatitis B carriers. Hepatitis B virus can be transmitted sexually as well as by transfusion (intravenous route). Transfusion transmitted diseases are the most common causes of transfusion associated morbidity and mortality.

Transfusion transmitted hepatitis is caused by blood transfusion. Hepatitis C virus and Hepatitis B virus are common agents. HBsAg was first discovered by Blumberg and his associates [1].

If pretesting of HBsAg detection done in collected blood bags than its transmission to community can be prevented and so it is made mandatory in our country to test for HBsAg prior to issue blood [2].

There are various methods for blood testing for HBsAg detection like Rapid diagnostic kit, ELISA, Molecular methods like PCR and FISH, Counter immunoelectrophoresis etc... Rapid kits and ELISA commonly used in blood banks and here we have done study to check usefulness of Rapid kits as compare to ELISA (considering ELISA as standard) for screening of collected blood bags.

MATERIALS AND METHODS

This study was carried out at tertiary care hospital, blood bank Gujrat, India from the date 01/01/2016 to 31/08/2016. We have tested total 10892 donor samples with using third generation ELISA kit as well as by rapid diagnostic kit.

Rapid diagnostic kit based on immunochromatography sandwich principle that includes a combination of monoclonal antibody gold conjugate (colloidal gold) and polyclonal solid phase antibodies which selectively binds HBsAg with high degree of sensitivity.

ELISA test is also for detection of HBsAg in serum or plasma which we considered as standard test. The positive HBsAg result by ELISA duplicated by

another person to prevent bias and confirm HBsAg positivity. Then we have also calculated sensitivity and specificity of rapid diagnostic test in comparison to that of ELISA method to evaluate efficacy for its use in blood bank.

The mean age group of donor and incidence of HBsAg in our blood bank was also calculated.

Table-1: Comparative Analysis of Rapid Versus ELISA

RAPID CARD TEST	ELISA TEST RESULT	
	REACTIVE	NON REACTIVE
REACTIVE	70	00
NON REACTIVE	10	10812

Then sensitivity, specificity, positive predictive value and negative predictive value were calculated.

The rapid diagnostic kit showing sensitivity of 87.5%, specificity of 100%, Positive predictive value of 100% and negative predictive value of 99.90%.

The mean age among 10892 donor was 29 year and maximum donor were males. Among donors 10177 donor were males and 715 were females reflecting male to female ratio of 14.2:01.

DISCUSSION

In Soman S.K et al study male to female ratio was of 11:01 that correlates with our study in which it is 14.2:01. The incidence of HBsAg positivity in our blood bank is approximately 0.8% which is lower than study of Jindal et al in 1989 and G. Nath *et al.* in 1991 [3, 4].

The false negative rate of rapid diagnostic test in our study is high. This could be because of reason that ELISA is highly sensitive and it detect lower concentration of HBsAg that can be missed by rapid diagnostic kit. This finding is not correlate with study of Sunil Ranga et al study in which rapid diagnostic methods were having low false negativity [5].

So this 10 sample that was non reactive by rapid card test due to low titer of antibody which we can be concluded because this 10 sample having low optical density value as compare to other 70 positive samples in ELISA.

The ELISA test having very high sensitivity, and specificity as compare to rapid kit. The disadvantage of ELISA is that it is time consuming and requires special training of staff and costly equipments. But it is perfect screening tool for blood donor testing and as it require more time cannot be used in emergency. The Rapid diagnostic kit having although slight less sensitivity as compared to ELISA, it can be

RESULTS

Among 10892 donor, by ELISA method 80 donor were reactive and were confirmed in duplicate result by another person. From this 80 reactive donor, 70 donors were positive by rapid diagnostic kit. Then results were tabulated as below.

performed in 15 to 20 minute and no special training needed so that can be used in emergency situation.

CONCLUSION

The rapid diagnostic test kits gives result in 20 minutes so that can be used in emergency situation when less time available to perform ELISA. When there is need for testing of blood sample prior to apheresis procedure or when emergency blood issue needs to be done, rapid diagnostic test useful and then subsequently can be tested by ELISA. But as sensitivity of rapid diagnostic test is 87.5% it cannot replace ELISA anyhow.

REFERENCE

1. Blumberg BS, Alter HJ, Visnich S; A new antigen in leukemia sera. *Jama*, 1965; 191(7): 541-546.
2. Choudhury N, Ramesh V, Saraswat S, Naik S; Effectiveness of mandatory transmissible diseases screening in Indian blood donors. *The Indian journal of medical research*, 1995; 101: 229-232.
3. Jindal N, Aggarwal A, Prabhakar H, Arora S; A Comparative Study of ELISA And Latex Agglutination Tests In Detecting HB sAg In Patients Of Viral Bepatitis, Voluntary Blood Donors And Healthy Pregnant Women. *Indian Journal of Medical Microbiology*, 1989; 7(04): 160.
4. Nath G, Sarkar M, Sanyal S; Hepatitis B Surface antigen and e antigen amongst blood donors in utter Pradesh, *Indian J Med. Microbiol*, 1991; 179.
5. Ranga S, Pandey J, Talib VH; Evaluation of two techniques (RPHA and Latex agglutination test) for use as a screening tool for HbsAg, *Indian J. Pathol Microbiol*, 1994; 37:4: 375.