Evaluation of ICT used in Screening of Donated Blood for Hepatitis B virus in Omdurman Maternity Hospital

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ABSTRACT

Introduction: The main mode of infection with Hepatitis B virus is blood is transfusion and its products but blood transfusion becomes a necessity in the clinical practice. Blood screening tests are the only reliable tools to exclude the infected blood. Continuous evaluation of these tests is important especially in centres with massive blood transfusion such as Omdurman Maternity Hospital.
Study Design: This study was a descriptive analytic hospital based one.
Study Objective: The aim of the study was to evaluate ICT used in screening donated blood for Hepatitis B sAg compared to ELISA as an accepted gold standard technique.

Material and Methods: Fifty venous blood specimens were collected from clinically eligible voluntary blood donors. Sera were harvested and each specimen was tested for Hepatitis B virus sAg by ICT and ELISA. Results were statistically analyzed.
Results: Sixteen serum specimens out of the fifty specimens were positive by ELISA. Nine serum specimens out of the same fifty specimens were positive by ICT. All serum specimens that were positive by ICT were also positive by ELISA.
Conclusion: In blood transfusion practice, ICT alone is not a sensitive test to exclude infected blood with Hepatitis B virus. However, it can be accepted as a reliable specific test.
Key words: Hepatitis B virus, ICT, ELISA, Omdurman

INTRODUCTION

The main mode of infection with Hepatitis B virus is blood transfusion and its products (1). Blood transfusion is a necessity in the clinical practice in spite of the high risk of transmission of infectious agents like Hepatitis B virus (2). Such a situation creates a need for safe blood transfusion (3). Screening tests are the only reliable tools to solve this problem (2, 3). In Sudan, the screening of the donated blood for Hepatitis B virus was introduced throughout the country in 2002, before which time screening was performed in only a few centres in Khartoum (4, 5, 6).

High sensitivity and specificity of the applied tests are of prime importance. Many tests procedures have been developed such as ICT and ELISA (3, 5, 6). However, continuous evaluation becomes part of the blood transfusion package. ELISA technique is more superior to ICT in blood screening but comparatively more expensive and skill demanding (7). It is the most common reliable workable technique in blood screening for infectious agents in blood such as Hepatitis B virus. Since the issue is about human health, ELISA technique deserves the expense.

Omdurman Maternity Hospital is a specialized obstetrics hospital with a wide catchment area. Many of the women attending the hospital need blood transfusion. In such a hospital with massive blood transfusion, the necessity for continuous evaluation to the blood screening techniques cannot be overemphasized.

Study Objective:

General Objective:

The aim of the study was to evaluate ICT used in screening donated blood for Hepatitis B sAg compared to ELISA as an accepted gold standard technique.

Specific Objectives

1. To estimate the prevalence of Hepatitis B virus infection in donated blood.
2. To determine the specificity and sensitivity of ICT compared to ELISA technique in blood screening for Hepatitis B virus.
3. To highlight the importance of the continuous evaluation of blood screening procedures for Hepatitis B virus.

MATERIALS AND METHODS

Study Design: This study was a descriptive analytic hospital based one.

Study Area: This study was conducted in Omdurman Maternity Hospital Blood Bank in Khartoum State, Sudan.

Study Population: It included all voluntary blood donors who were eligible for blood donation according to the clinical assessment.

Study Sample:

The study sample was composed of 50 blood donors randomly selected from the population.

Selection Criteria:

Inclusion Criteria:

1. Eligibility for blood donation.
2. Valid consent of the donor for participation in the study.

Exclusion Criteria:

1. Initial refusal of the blood donor to participate in the study.
2. Termination of the participation by the blood donor.

Specimens Collection:

Five milliliters of blood were collected by venepuncture and immediately each 2.5 ml were delivered into a sterile, clean dry blood container. The containers were left for three hours on the bench at room temperature for the blood to clot. Sera were separated from the clotted blood by centrifugation at 3000 rpm for ten minutes. The harvested sera were put into serum aliquots and stored at 2 degrees Celsius until tested. For each participat's specimen; one part was tested for HBsAg by ELISA and the other by ICT.

Testing Procedures:

All the conditions for the storage of the kits were strictly followed. The sera were brought to room temperature just prior to analysis. . All the tests

were done in one go and performed as per manufacturer's instructions. The results were read and recorded by two independents medical technologists and supervised by a consultant.

Enzyme link immune-sorbent assay (E L I S A):

Principle:

The method used was a one step enzyme immunoassay, based on the principle of sandwich type using monoclonal and polyclonal antibodies selected for their ability to bind themselves to the various subtypes of Hepatitis BsAg.

Immunochromatographic test (I C T):

Principle:

Immunochromatographic test used was a one step assay designed for qualitative detection of Hepatitis BsAg in human serum or plasma.

Ethical Clearance: Formal acceptance of the hospital authority and the consent of each participant were obtained. The collected blood specimens and any other data were used only for the purpose of this declared study and not passed to any third party. All the blood residuals and waste products were appropriately treated and safely disposed.

RESULTS

Nine serum specimens out of 50 specimens were found to be positive by ICT. Sixteen specimens were found to be positive by ELISA. All serum specimens that were positive by ICT were also positive by ELISA.

Table 1: showing the results by ICT and ELISA

Result	ICT (n=50)	ELISA(n=50)
Positive	9	16
Negative	41	34

Table 2: showing ICT parameters compared to that of ELISA

Parameter	Value
Sensitivity	56%

Specificity	100%
Positive predictive value	100%
Negative predictive value	85%

DISCUSSION

The prevalence of seropositivity of Hepatitis B virus by ELISA was 32%. Elshafie in Gezira, Sudan reported a prevalence of 17.3% in blood donors (8). Sudan has been classified among the African countries with high Hepatitis B virus endemicity (4, 6, 8, 9). The prevalence ranges from one area to another (6). High prevalence can be significantly reduced if immunization programme is widely launched.
The two main tests commonly used for blood screening are ICT and ELISA. ELISA is considered as the gold standard test (7, 10, 11). The ICT used in this study had a sensitivity of 56% which agreed with different reports (6. 7). Taking into account the deduced ICT parameters compared to ELISA, ICT is not a reliable test for excluding infected blood because it is of low sensitivity (56%) and low negative predictive value (85%). About 15 % of the specimens that were negative by ICT could be positive to Hepatitis B sAg according to its negative predictive value. We found that ICT had a sensitivity of 100% and also a positive predictive value of 100%. In this aspect, ICT is a reliable test when the result is positive. Such a finding agreed with a report by Khan in Pakistan (7). According to the documented literature, there is a residual risk of transfusing infected blood if it is donated during the window period (pre-seroconversion) even ELISA result is negative (12, 13). More advanced techniques such as PCR can be used to back ELISA in Hepatitis B virus negative blood of at risk donors.

Conclusion:

In blood transfusion practice, ICT alone is not a sensitive test to exclude Hepatitis B virus infected blood while it can be a reliable specific one. In spite of considering ELISA as the gold standard test in blood screening for HBsAg, some infected blood may be transfused if it is donated during the window period (pre-seroconversion). More advanced techniques such as PCR are needed to resolve any doubt in the clinical profile of at risk donors even ELISA test is negative.

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Disclaimer

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REFERENCES

1. Geo F. Brooks, Karen C., Karroll Janet Butel S. , Stephen A. Morse, Hepatitis viruses, Jawetz, Medical Microbiology, twenty fourth edition, McGraw Hill, 2007, 446-485.

2. A.V.Hoffbrand, P.A.H. Moss and J.E.Pettit (2006). Essential Haematology, fifth edition: Chapter 23, Bleeding disorder caused by vascular and platelet abnormalities. (pp.278-289)

3. Possible risks of blood product transfusions. American Cancer Society. http://www.cancer.org/docroot/ETO/content.

4. Mudawi, H. M. Y., H. M. Smith, S. A. Rahoud, I. A. Fletcher, O. K. Saeed, and S. S. Fedail. 2007. Prevalence of hepatitis B virus infection in the Gezira State of Central Sudan. Saudi J. Gastroenterol. 13:81-83.

5. Blood safety indicators, 2007, Geneva, World Health Organization.

6. SHAZA MAHGOUB ET AL, HEPATITIS B VIRUS (HBV) INFECTION AND RECOMBINATION BETWEEN HBV GENOTYPES D AND E IN ASYMPTOMATIC BLOOD DONORS FROM KHARTOUM, SUDAN, J. CLIN. MICROBIOL. JANUARY 2011 VOL. 49 NO. 1 298-306

7. Khan J.K. et al, Evaluation of the Performance of Two Rapid Immunochromatographic Tests for Detection of Hepatitis B Surface Antigen and Anti HCV Antibodies Using Elisa Tested Samples, SPECIAL EDITION ANNALS VOL 16. NO.1 JAN. - MAR. 2010 87

8. Elshafie SS, The prevalence of hepatitis B surface antigen in the Gezira (Sudan). Afr J Med Sci, 1992 Oct; 21(1):61-3.

9. Mustafa AA Abou, Yassir M Eltahir and Abdelwahid S Ali, Seroprevalence of Hepatitis B virus and Hepatitis C virus among blood donors in Nyala, South Dar Fur, Sudan.

10. Abou, M. A., Y. M. Eltahir, and A. S. Ali. 2009. Seroprevalence of hepatitis B virus and hepatitis C virus among blood donors in Nyala, South Dar Fur, Sudan. Virology J. 6:146.

11. Nagi AM, Altyeb HA, Ahmed AM: Seroprevalence of Hepatitis B and C Viral Infections among blood donors in Shendi, River Nile State, Sudan. *RESEARCH JOURNAL OF MEDICINE AND MEDICAL SCIENCES* 2007, 2(2):122-126.

12. Allain, J.-P. 2004. Occult hepatitis B virus infection: implications in transfusion. Vox Sang. 86:83-91.

13. Raimondo G, Pollicino T, Cacciola I, Squadrito G: Occult hepatitis B virus infection. *J HEPATOL* 2007, 46:160-170.

