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Comparison of ELISA and NAT techniques among blood donors

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Abstract
Large number of blood transfusions are carried out globally to save countless lives, but unsafe practices risks the recipient of transfusion transmittable infections ((TTI'S). TTI's can be reduced by improving donor selection, donor awareness regarding TTI and implementing sensitive screening tests. In India, it is mandatory to test each donated unit of blood for markers of HIVI and II, HBV, HCV, malaria and syphilis. Currently, in India all the blood donations are screened for various infectious markers using ELISA or rapid methods. TTIs can be responsible for causing considerable burden on the health status and economy of the country. Hence there is need to introduce better methods for testing blood units. Even after being seronegative the blood transfusions are still at risk of transmitting infections. In order to reduce the residual risk sensitive screening tests are needed and as a result NAT has been considered. In India NAT testing is not mandatory but many private blood banks and hospitals and state Governments of few states have started implementing NAT for blood safety. It increases the possibility of identifying the infection in window period and thus reducing the residual risk of TTIs. NAT is highly sensitive and specific for viral nucleic acids and is based on amplification of targeted regions of RNA and DNA and thus is the technique of choice. By early detection than serology, the window period of HIV, HBV and HCV infections narrows. But the issue of higher cost accounts for its limited use especially in developing countries. The present study is designed to understand the role of NAT in detecting the risk acquiring TTIs as compared to conventional methods currently in use for detection of HBV, HCV and HIV infections amongst blood donors.

Keywords: Nucleic acid testing, transfusion transmitted infections, blood transfusion

Introduction
Blood transfusion is most important part of medical treatment and it's also associated with risk of transfusion transmitted infections (TTIs). Hence screening of blood bags is important to ensure safe blood transfusion. An effective donor screening, sensitive screening tests can reduce the risk of acquiring TTI's. Large number of blood transfusions are carried out globally to save countless lives [1], but unsafe practices risks the recipient of transfusion transmittable infections((TTI'S). TTI's can be reduced by improving donor selection, donor awareness regarding TTI and implementing sensitive screening tests [2]. In India, it is mandatory to test each donated unit of blood for markers of HIVI and II, HBV, HCV, malaria and syphilis [3]. Currently, in India all the blood donations are screened for various infectious markers using ELISA or rapid methods. TTIs can be responsible for causing considerable burden on the health status and economy of the country [4]. Hence there is need to introduce better methods for testing blood units. Even after being seronegative the blood transfusions are still at risk of transmitting infections. In order to reduce the residual risk sensitive screening tests are needed and as a result NAT has been considered. In India NAT testing is not mandatory but many private blood banks and hospitals and state Governments of few states have started implementing NAT for blood safety [5, 6]. It increases the possibility of identifying the infection in window period and thus reducing the residual risk of TTIs [4]. NAT is highly sensitive and specific for viral nucleic acids and is based on amplification of targeted regions of RNA and DNA and thus is the technique of choice. By early detection than serology, the window period of HIV, HBV and HCV infections narrows. But the issue of higher cost accounts for its limited use especially in developing countries [4]. The present study is designed to understand the role of NAT in detecting the risk acquiring TTIs as compared to conventional methods currently in use for detection of HBV, HCV and HIV infections amongst blood donors.

Materials and Methods

The present study was carried out in Department of General Medicine. SSPM Medical College, Padve Sindudurgh, Maharashtra.

The blood collections were carried out from the voluntary donors at outdoor blood donation camp and in-house blood bank as well as from replacement donors at blood bank. Trained personnel carefully selected the donors for donation after a complete physical examination and satisfactorily answering the donor's questionnaire according to blood donor selection criteria and guideline from drug and cosmetic act and NACO. On completion of blood donation, the units were screened for the five commonest TTIs namely HIV I & II, HBsAg, HCV, syphilis and malaria. Screening test ELISA and Rapid Kit were used for HIV I & II, HBsAg, HCV. Screening test Rapid Kit and Peripheral smear were used for Malaria. VDRL is used for screening Syphilis. The reactive sample was retested in duplicate before considering it seropositive. Seropositive blood bags were discarded. All non-reactive samples are sent for confirmation testing by NAT technique for HIV I & II, HBsAg, HCV to reduce the risk of transfusion transmitted infections (TTIs) in the recipients, thus providing an additional layer of blood safety. The data were recorded on specially formed proforma, the recorded data were tabulated and analysed. For comparing NAT and Elisa as suggested by the statistician Cohen's Kappa Coefficient, statistical test is used.

Results

Our study was a 2 years non-interventional retrospective study and the data was collected from the Blood Bank. During the study period total of 1193 donors donated the blood.

The age of the blood donors in the present study ranged from 20 - 50 years Out of the total screened blood units 09 were seropositive for the transfusion transmitted infection.

Among the 09 seropositive donors, 4 were positive for HBV infection and out of those 3 were HbsAg positive and 4 seropositive donor which was not detected by the serological test was detected by the NAT. Statistically using Cohen's Kappa coefficient, it was noted that the strength of agreement between ELISA and NAT can be considered to be very good.

Table 1: Positive using Elisa

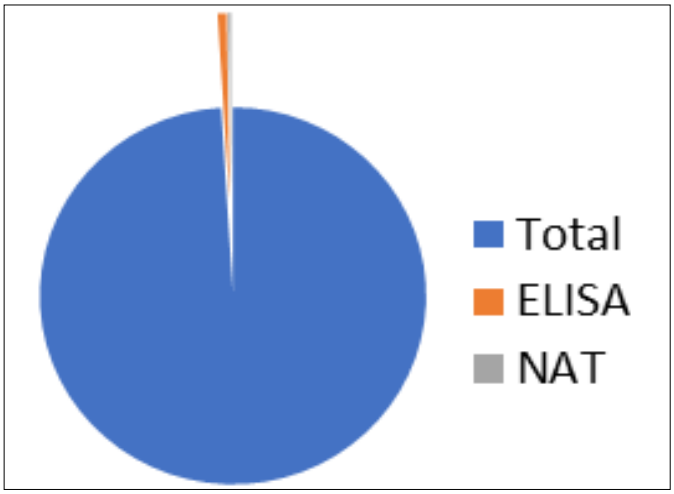
HIV	HBV		HCV
	HbsAg	HBV	
2	03	04	0

Table 2: Positive using NAT

HIV	HBV		HCV
	HbsAg	HBV	
1	0	01	1

Table 3: Test for significance

Total	ELISA	NAT	P value (Sig)
1193	09	03	<0.005 Sig



Graph 1: Difference

Discussion

Nucleic acid testing (NAT) is a molecular technique for screening blood donations to reduce the risk of transfusion transmitted infections (TTIs) in the recipients, thus providing an additional layer of blood safety. It was introduced in the developed countries in the late 1990s and early 2000s and presently around 33 countries in the world have implemented NAT for human immunodeficiency virus (HIV) and around 27 countries for hepatitis B virus (HBV). NAT technique is highly sensitive and specific for viral nucleic acids. It is based on amplification of targeted regions of viral ribonucleic acid or deoxyribonucleic acid (DNA) and detects them earlier than the other screening methods thus, narrowing the window period of HIV, HBV and hepatitis C virus (HCV) infections. NAT also adds the benefit of resolving false reactive donations on serological methods which is very important for donor notification and counseling. This study is one such effort to find the best way to diagnose. Blood Banks are likely to work more efficiently if the NAT technologies are implemented which will help in intercepting potentially harmful infectious pathogens while continuing to provide on time blood availability for patients and to the hospital.

Conclusion

As NAT implementation reduces the rate of TTIs, its implementation will gain more speed in many more countries as a valuable addition to existing safety efforts.

References

1. Jasani J, Patel V, Bhuva K, Vaihhani A, Patel H. Seroprevalence of transfusion transmissible infections among blood donors in a tertiary care hospital. Int. J Biol Med Res. 2012;31:1423-5.
2. Bihl F, Castelli D, Marincola F, Dodd RY, Brander C. Transfusion-transmitted infections. Journal of translational medicine. 2007;5(1):25.
3. Standards for Blood Banks & Blood Transfusion Services, [1] National AIDS Control Organization, Ministry of Health and Family Welfare, Government of India, New Delhi, 2007.

4. Shriva S, Tava M, MiShra S. Nucleic Acid Amplification Testing (NAT): An Innovative Diagnostic Approach for Enhancing Blood Safety.
5. Hans R, Marwaha N. Nucleic acid testing-benefits and constraints. Asian journal of transfusion science. 2014;8(1):2.
6. Makroo R, Choudhury N, Jagannathan L, Parihar-Malhotra M, Raina V, Chaudhary R, et al. Multicenter evaluation of individual donor nucleic acid testing (NAT) for simultaneous detection of human immunodeficiency virus-1 & hepatitis B & C viruses in Indian blood donors. Indian Journal of Medical Research. 2008;127(2):140.
7. O'brien SF, Yi QL, Fan W, Scalia V, Kleinman SH, Vamvakas EC. Current incidence and estimated residual risk of transfusion-transmitted infections in donations made to Canadian Blood Services. Transfusion. 2007;47(2):316-25.
8. Giri PA, Deshpande JD, Phalke DB, Karle LB. Seroprevalence of transfusion transmissible infections among voluntary blood donors at a tertiary care teaching hospital in rural area of India. Journal of family medicine and primary care. 2012;1(1):48.
9. Chandrasekaran S, Palaniappan N, Krishnan V, Mohan G, Chandrasekaran N. Relative prevalence of hepatitis B viral markers and hepatitis C virus antibodies (anti HCV) in Madurai, south India. Indian journal of medical sciences. 2000;54(7):270-3.
10. Jain R, Aggarwal P, Gupta GN. Need for nucleic acid testing in countries with high prevalence of transfusion-transmitted infections. ISRN hematology, 2012.