

Comparison of ELISA and NAT Techniques among Blood Donors

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Abstract

Blood transfusion is most important part of medical treatment and is also associated with risk of transfusion transmitted infections (TTIs). Hence screening of blood bags is important to ensure safe blood transfusion. The present study was done to evaluate the ability of nucleic acid testing (NAT) and to compare it with ELISA assay to detect Window period for HBV, HCV, and HIV in the donor population of the blood bank of Karwar institute of Medical sciences, Karwar, Karnataka. A total of 3183 donors were screened over 4 ½ years to assess the seroprevalence of infectious disease markers. Blood units were screened for the five commonest TTIs namely HIV I & II, HBsAg, HCV syphilis and malaria using screening test like ELISA and Rapid Kit, peripheral smear and VDRL tests. All reactive sample were retested. Seropositive blood bags were discarded. All non-reactive samples were sent for confirmation testing by NAT technique for HIV I & II, HBsAg, HCV to reduce the risk of TTIs in the recipients, thus providing an additional layer of blood safety. Out of 3183 blood donors, 17 were seropositive for the TTIs. Totally 14 units were positive for HBV infection, out of those 13 were detected HbsAg positive by ELISA and 1 seropositive donor which was not detected by the serological test was detected by the NAT. NAT implementation is likely to reduce the TTIs and its implementation will be a valuable addition to the existing safety efforts.

Keywords: Nucleic acid testing, Transfusion transmitted infections, Blood transfusion.

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INTRODUCTION

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 at blood bank, Karwar Institute of medical Sciences, Karwar. It was a four and half year (July 2013 to December 2017) non-interventional, retrospective, observational study. 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 to Bowring and Lady Curzon Hospital, Bangalore 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 four and half year (July 2013 to December 2017) non-interventional retrospective study and the data was collected from the Blood Bank. During the study period total of 3183 donors donated the blood.

Out of 3183 blood donors, all were voluntary donors. Out of the total donors 102 were females and rest that is 3081 were Male. The age of the blood donors in the present study ranged from 18 – 64 years and 75.43% of the donors were in the age group of 20 to 39 years. Out of the total 3183 screened blood units 17 were seropositive for the transfusion transmitted infection, giving the percentage of 0.53%

Among the 17 seropositive donors, 14 were positive for HBV infection and out of those 13 were HbsAg positive and 1 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.

Seropositive blood donors					
HIV	HBV		HCV	Syphilis	Malaria
	HbsAg	NAT HBV			
0	13	1	0	2	1

DISCUSSION

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. Out of the total 3183 screened blood units 17 (0.53%) were seropositive for the transfusion transmitted infection. There was 100 % voluntary blood

donation in our study. A number of studies have showed lower prevalence of TTI'S among voluntary donors compared with other types of donors, with the lowest rates among regular donors.

In our study out of total 3183 donors, 3081(96.79%) were male and only 102 (3.70%) were female donors. There were similar results in other studies where there was male predominance in blood donation lesser number of female donation may be because of donor referrals attributed to Anaemia and underweight [7, 8].

In our study, HBV was the most prevalent life-threatening TTI, is also associated with a carrier state and chronic liver disease. The prevalence of HBsAg is high in INDIA even in spite of the availability of effective vaccine. Seroprevalence of HBsAg in various other Indian studies has been shown to range between 1.86% to 4% [9]. The incidence of HBsAG was 0.43 %, in our study. Increased risk of HBV infection through transfusion is higher because of a long window period between initial HBV infection and the detection of HBsAg , therefore it is necessary to detect window period by highly sensitive technique like NAT. Out of 3183, seronegative donations were 3167, which were sent to Bowring and Lady Curzon Hospital, Bangalore 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. In which 1 was detected to be positive for HBV infection. Thus, accounting for total of 14 HBV positive donors. The risks and implications of TTIs in developing countries remain substantial.

Combined NAT yield in two of the studies done in India was 0.034% and 0.065%. Results were high when compared to studies from developed countries [6, 10]. In our study, one donor was found to be positive for NAT HBV and NAT yield was 0.031%. India with large population, it is likely that the adoption of NAT can have a significant impact on the rate of TTIs.

CONCLUSION

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. 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.

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