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Original Research Article

Safe Blood transfusions: Still a risk in India?

Manjunath MR[1*], Malathi BG[2], Muralidhar Bhat Y[2], Shivakumar S[3], Deepa S[4]

[1]Assistant Professor, Department of Pathology, Mandya Institute of Medical Sciences, Karnataka, India

[2]Associate Professor, Department of Pathology, Mandya Institute of Medical Sciences, Karnataka, India

[3]Professor and Head, Department of Pathology, Mandya Institute of Medical Sciences, Karnataka, India

[4]Assistant Professor, Department of Microbiology, Mysore Medical College and Research Institute, Karnataka, India

*Corresponding author email: drmanju26@gmail.com

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Abstract

Introduction: Nucleic acid testing (NAT) is the latest approved method for detection of transfusion transmitted infections. With higher prevalence of infections in window period and occult infections, blood safety can be compromised when testing is done using only serological techniques. With this background this study had been taken up to compare the results of serological tests with NAT.

Material and methods: Voluntary blood donations were screened for hepatitis B, hepatitis C and human immunodeficiency virus using ELISA. All samples were sent for ID-NAT and results of both methods were compared, analyzed individually.

Results: A total of 11,393 blood units were collected during the study period. ELISA test results showed 176 (1.54%) positivity for these transfusion transmitted infections (TTIs) in total. Among them, 133 (75.56%) was HBV, 22 (12.5%) was HCV and 21 (11.93%) was HIV as shown by ELISA. ID-NAT test results showed 174 (1.52%) positive in total. As analyzed by individual test results, 37 (0.32%) of total blood samples showed positivity in NAT which showed negative results in ELISA. Also 38 (0.33%) of total blood samples (HBV = 27, HCV = 08, HIV = 03) which showed positivity in ELISA were negative in NAT.

Conclusion: ID-NAT is definitely a useful screening method for HBV, HCV, HIV. It clarifies infections in window period, occult infections and false seroreactive cases.

Key words

Blood, ID-NAT, ELISA, Transfusion transmitted infections.

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Introduction

Over the past decade, the pendulum of blood safety policy has swung wide and hit hard. The importance of blood safety has been highlighted all around the world. The major threats to blood safety are the potential of transfusion transmitted infections (TTIs) caused by blood borne viruses, including hepatitis B virus (HBV), human immunodeficiency virus (HIV) and hepatitis C virus (HCV) [1].

Nucleic acid testing (NAT) is a molecular technique for screening blood donations to reduce the risk of TTIs in the recipients, thus providing an additional layer of blood safety [2]. The introduction of NAT for screening pooled or individual donations has led to improved blood safety all over the world. NAT systems are able to shorten the diagnostic window period to a minimum and to increase blood safety to the highest standard [3, 4].

In India, mandatory blood screening for HBV, HIV and HCV is done by serological tests for HBsAg and antibodies to HIV1/2 and HCV [5]. The screened seronegative donations are still at risk for TTIs. Thus, the need for a sensitive screening test arises to decrease this residual risk which has been reduced significantly over the last few years where NAT has been implemented. NAT testing has been started in few centers in India, but it is not a mandatory screening test for TTIs as per Drug and Cosmetics Act, 1940 and the rules therein. Major barriers in implementing routine NAT testing in India are its high cost and lack of technical expertise in most of the blood centers [2].

Our institute is a tertiary care centre which caters more than 10,000 blood units per year to surrounding areas. We are privileged by using both serological tests and also NAT tests for screening these blood donations as supported by our government. This study has been taken up to compare the results of serological tests with NAT tests.

Material and methods

This study was conducted in district hospital blood bank attached to Department of Pathology, Mandya Institute of Medical Sciences. Study included a period of 20 months from October 2012 to may 2014. All voluntary donations had been screened for HIV1 and HIV2, HBV and HCV infections. The screening for HIV was done by ELISA using kits (Pareekshak HIV ELISA kit, India). HBsAg (Surface antigen) was detected by (Hep-scan, India). Anti HCV test was done by ELISA (Hep-scan, India). Manufacturer's instructions were followed. All blood units irrespective of the tests were sent to conduct ID-NAT investigation with proper labelling. Results are documented and analyzed.

Results

A total of 11,393 blood units were collected during the study period. All the units were tested for HIV1 and HIV2, HBV and HCV infections. ELISA test results showed 176 (1.54%) positive for these TTIs in total. Among them, 133 (75.56%) was HBV, 22 (12.5%) was HCV and 21(11.93%) was HIV as shown by ELISA. ID-NAT test results showed 174 (1.52%) positive in total. As analyzed by individual test results, 37 (0.32%) of total blood samples showed positivity in NAT which showed negative results in ELISA. Also 38 (0.33%) of total blood samples (HBV = 27, HCV = 08, HIV = 03) which showed positivity in ELISA were negative in NAT.

Discussion

A high standard of viral safety of blood transfusion has to be guaranteed while using

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well validated test systems for viruses like HIV, HCV, HBV infections. NAT is said to be very sensitive method of detection of viral RNAs /DNAs. For safety blood donations this test has been adopted by our government.

Our study has reported, 1.54% of positivity for TTIs by using ELISA method. This serological method has specificity of <100%. Due to this factor and now a day for identification of infections in window period, ELISA results are counter checked by newer sensitive techniques like NAT. ELISA is still a method of choice in our country due to its cheaper cost and wide availability.

Ours is a government institution and our government has taken up ID-NAT for screening all blood units at government hospitals. We have sent all the blood samples for NAT & the results were 1.52% positivity of the total blood samples.

When we compared the results of each sample, 37 (0.32%) samples showed positive in NAT which were negative in ELISA. This is explained as the donors might be in window period or in occult infections. This was the strong reason where NAT has been approved as a highly sensitive test which detects infection in window periods. This test simultaneously detects human immunodeficiency virus-1 (HIV-1), hepatitis B virus (HBV) and hepatitis C virus (HCV) in samples of donor blood [6].

The introduction of HBV NAT in the United States, along with the HBV vaccination policy made a measurable contribution to blood safety and decreased residual risk of HBV infection [7]. In United Kingdom, NAT has reduced the risk of HCV by 95% and that of HIV by 10% [8]. A study in china has reported that Implementation of NAT will provide a significant increment in safety relative to serological screening alone [9].

A study in India concluded that ID-NAT is ideal methodology for TTIs screening [6]. In India blood banks are gradually introducing NAT to provide safe blood to their patients. First multi-centric study was done where a total of 12,224 samples along with their serological results were obtained from eight blood banks in India and were tested individually and manually for HIV 1, HCV and HBV. They observed eight NAT yield cases [10]. According to a study from the western part of India combined NAT yield (NAT reactive/seronegative) for HIV, HCV and HBV was 0.034% which is high when compared to studies from developed countries [11]. In another study conducted in north India, 18,354 donors were tested by both ID-NAT and fourth generation enzyme-linked immunosorbent assay (ELISA), 7 were found to be NAT-positive but ELISA-negative for HBV and HCV 0.038% [12]. This high yield of NAT is due to the high prevalence of TTIs in India, further highlighting the need for NAT in India. In another study from a tertiary care center from north India ID-NAT results were compared to serological method for 73,898 samples, 1.49% were reactive by NAT, HIV-1 (0.09%), HCV (0.25%), 1.05% were reactive for HBV only [13].

NAT is a highly sensitive and advanced technique which has reduced the window period but it is highly technically demanding, involving issues of high costs, dedicated infrastructure facility, equipments, consumables and technical expertise. The need for NAT depends on the prevalence and incidence rate of infections in blood donor population, available resources and the evidence of benefit added when combined with serology tests. Hence the decision of starting NAT should be considered when basic quality assured blood transfusion system is already in place.

In our study, 38(0.33%) samples were shown positive in ELISA were proved negative in NAT.

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This false reactivity in serology has lots of controversies. NAT also adds the benefit of resolving false reactive donations on serological methods, which is very important for donor notification and counselling. In a recent Malaysian study, 1388 donor samples were tested by serology as well as NAT, authors found 1.37% samples reactive on standard serology methods but non-reactive by NAT. These samples were confirmed to be "false reactive" on confirmatory serological tests [14]. But in our study, these false reactive samples were not confirmed by any other tests to prove them.

Indian blood donors show moderate prevalence rates for the infectious viruses: HIV (0.3%), HCV (1.98%), and HBV (1.2%). The predominant Indian HBV genotype is genotype D, which is associated with very low viemia, high prevalence of Occult HBV, and low viral load. In our study, 27 cases of HBV were NAT negative with seroreactivity. Low viremia and higher prevalence of HBV within Indian population, underlines the importance of a highly sensitive nucleic acid testing (NAT) blood screening assay for HBV. Probably a single tube system in ID-NAT which interferes with for better results or we require a enhanced sensitive NAT assay for HBV detection is yet to be determined?

Even vaccination which is available for only HBV is that a point in false reactivity or it might be lower viremia for ID-NAT to detect HBV is a point of concern. We need more clarifications about this matter which is of concern .More studies require to solve this puzzle and help us, as we are in early steps of the ladder in research.

Conclusion

ID-NAT is a definitive useful screening for safety blood donations. False reactivity will be solved by NAT. Highly sensitive NAT is required for HBV screening to detect low viremia cases.

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