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MINIPOOL NAT YIELD IN BLOOD DONOR'S SCREENING USING A SENSITIVE MULTIPLEX ASSAY IN A TERTIARY CARE HOSPITAL OF SOUTHERN RAJASTHAN, INDIA

Transfusion Medicine

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ABSTRACT

Background & Objectives Nucleic acid amplification testing (nucleic acid testing [NAT]) for blood donor screening is progressively being embraced in India to minimize the risk of transfusion-transmitted diseases. This study was aimed at assessing the yield of minipool NAT testing for hepatitis B, hepatitis C, and human immunodeficiency virus (HIV) in blood donors from Southern Rajasthan, India. **Methods** Samples from routine blood donors that were seronegative for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV), Syphilis and Malaria were collected from 1st January 2022 to 31st December 2022. These samples were further screened by NAT in pools of six donations (MP6) using the cobas TaqScreen MPX Test, version 2.0 (MPX2) on the cobas s201 System. Samples of reactive pools were retested to identify the reactive donation(s). **Results** Of 8559 seronegative donors, 09 were NAT reactive: 06 HBV, 02 HIV, 00 HCV and 01 co-infected with HBV and HCV. The overall NAT yield was 0.10%, with individual virus yield rates of 1/1222 for HBV and 1/2853 for HIV. **Conclusion** This is a study, using pooled samples screened with a highly sensitive automated molecular screening system, which shows the importance of identifying potentially infectious donations before they enter the blood supply and where a significant proportion of the blood collected is processed into components. In this study, we interpreted that NAT can assist to bring down the biggest infectious hazard to the safety of the blood supply i.e. HBV, HIV and HCV.

KEYWORDS

Blood donor screening, Minipool, NAT yield, Nucleic Acid Test,

INTRODUCTION

Blood transfusions are an integral element in the present scenario of healthcare system. However, transfusion of blood and its components is associated with various inherent risks which may range from mild to life threatening.[1] Transmission of known and unknown blood borne pathogens would result in additional morbidity as well as increased financial burden to the patient and society.

Transfusion transmitted infections (TTIs) are attributed as a major risk factors in the transfusion of blood and blood components, particularly in cases requiring multiple transfusions.[2] Good quality control practice starting from history taking to laboratory practices, and an integrated strategy for blood safety like collection of blood only from voluntary, nonremunerated blood donors and screening for TTIs can reduce such events.[3]

National blood policy of India recommends that screening of all blood donations should be mandatory for HIV-1 and HIV-2, Hepatitis B, Hepatitis C, Syphilis and Malaria.[4]

Majority of the blood centres in India perform the transfusion transmitted infections (TTIs) screening for Hepatitis B, Hepatitis C and HIV-1 and HIV-2 by ELISA and/or rapid methods in which the window period ranges from 21days to 60 days. Few medical centres have started Nuclei Acid Amplification Testing (NAT) for the purpose of blood safety because the window period is shortened for various viral infections (HIV, HBV and HCV) as NAT being a more sensitive test than ELISA test.[5]

NAT is a highly sensitive test as it relies on amplification of intended regions of viral nucleic acid for detection which succeeded in reducing the window period of HIV to 2.93 days, HCV to 1.34 and HBV to 10.34 days and thus, definitely helps in improving the transfusion safety. Adoption of NAT cost-effectively by single centre testing in a referral laboratory would certainly reduce the disease burden in the society whereas early diagnosis and management would lead to overall health benefit to both donors and patients.[6]

AIM OF THE STUDY

This study was aimed at assessing the yield of minipool NAT testing for Hepatitis B, Hepatitis C, and Human immunodeficiency virus (HIV) in blood donors from Southern Rajasthan.

MATERIAL & METHODS

Samples were collected from blood donors of a hospital based blood bank in Southern Rajasthan, India from 1st January 2022 to 31st December 2022, for routine serology. All donations nonreactive by serology were further tested by NAT (Minipool). A total of 8626 donations were collected and underwent serology screening for HBV, HCV, HIV, Syphilis and Malaria. Of these: 56.74% (4895/8626) were from repeat donors, the remainder 43.26% (3731/8626) from first time donors; 67.37% (5811/8626) were from voluntary donors, the remainder 32.63% (2815/8626) from replacement donors; and 94.83% (8180/8626) were from male donors while remaining 5.17% (446/8626) were female donors.

Serological screening was performed, following routine procedures, for: HBsAg (Hepalisa; sensitivity 100%), HCV Ab (HCV Microlisa; sensitivity 100%), HIV Ag/Ab (Microlisa-HIV Ag & Ab; sensitivity 100% in confirmed antibody positive samples) all from J. Mitra &Co. Pvt. Ltd.,Syphilis (RPR-Beacon Diagnostics Pvt. Ltd., Navsari, India); Malaria antigen (Satya2.0 PF/PV device,Viola Diagnostic Systems, Uttarakhand, India). All assays were performed according to the manufacturer's instructions.

Any donation found to be initially screen reactive for any of the serological targets was considered "serology screen positive" and NAT was not performed on these donations.

NAT was performed using the cobasTaqScreen MPX Test, version 2.0 for use on the cobas s201 System (MPX2) (Roche Molecular Systems, Branchburg, NJ, USA) including the automated Hamilton MICROLAB® STARlet IVD Pipettor sample pooler. The MPX2 assay detects HIV-1 Group M RNA, HIV-1 Group O RNA, HIV-2 RNA, HCV RNA, and HBV DNA and uses the polymerase chain reaction technology.

NAT was performed on the pools of six samples (MP6) following the manufacturer's instructions for the assay and automated platform.[7] Reactive pools were resolved by retesting the six donations individually to identify the reactive donation(s). The result of the MPX2 test is reported as reactive for a specific target(s), i.e. HBV, HCV, or HIV.

RESULTS

Serological screening was reactive on 1.22% (106/8626) donations. No further investigations were performed on these screen-reactive donations. Out of 106 seroreactive cases, 57 were HbsAg reactive, 08 were HIV reactive, 02 were HCV reactive and 39 were Syphilis reactive. No single case was found seroreactive for Malaria.

A total of 8520 donations were screened for viral nucleic acids, as 106

donations were excluded due to initial serological screen reactivity for HIV, HBV, HCV, Syphilis and Malaria .

A total of 0.10% (09/8520) donations were NAT reactive. Out of these NAT reactive donations, 33.33% (03/09) were voluntary and remaining 66.66% (06/09) were replacement donations. Of the 09 NAT reactive donations, 06 were HBV reactive, 02 were HIV reactive, 00 were HCV reactive and one of these was found to have dual infections (HIV and HBV), identifying a total of 10 infections in the 09 donations.

DISCUSSION

Nucleic acid amplification testing (nucleic acid testing [NAT]) for blood donor screening is progressively being embraced in India to minimize the risk of transfusion-transmitted diseases. The high sensitivity of NAT permits testing of a large volume of donations in a minipool format there by bringing down the expenses of testing compared to individual donation testing.

Prevalence of TTI in India is 1.8 - 4%, 0.4 - 1.09%, 0.2 - 1%, and 0.05 - 0.9% for HBV, HCV, HIV and Syphilis respectively.[8]

Based on initial pool reactivity with subsequent pool resolution, of 0.10% with individual virus yield rates of 1/1217 for HBV, 1/2840 for HIV and 00 for HCV. Not surprisingly, given the high incidence and prevalence of HBV in India, the greatest yield is for HBV. These data are in general agreement with other published Indian blood screening NAT data, a finding that is important as the data in the current study were generated using pooled NAT. This demonstrates the high yield of NAT screening by pooled NAT in India when using an assay with high sensitivity for HBV, such as the cobasTaqScreen MPX Test, v2.0.

The NAT yields vary between published reports from India, due to variations observed in donor populations and to a certain extent attributed to assay performance. A study done by Makroo et al. (2008) showed NAT yield of 0.06% (08/12023) (one HIV, zero HCV and 06 HBV cases and one HIV and HCV coinfection).[9]

Another study was conducted by Agarwal et al (2013) in which 73,898 blood donors were simultaneously screened by both NAT and ELISA/Rapid test for TTIs, NAT detected 121 cases (one HIV, 37 HCV, 73 HBV and 10 HBV-HCV co-infection) that were not detected by ELISA/Rapid tests showing a NAT yield of 0.16%.[10]

One study by Hans et al (2014) showed NAT yield of 0.09% (162/167069) (114 HBV, 43 HCV, 01 HIV and 04 HCV-HBV coinfection).[11]

CONCLUSION

Ensuring high standards of blood safety and uniformity in blood transfusion services is a challenge in vast and diverse country such as India.

Focusing on encouraging the voluntary nonremunerated blood donations instead of replacement blood donors by creating public awareness, vigilance of error, education and motivation should be an ideal working strategy.

Improving the number of female blood donors should be a priority as below 6% female donations in a country with more than 48% female population is quite low. Motivating women, creating awareness and eradicating any false beliefs are steps in forward direction.

Implementation of NAT for screening of all seronegative ELISA samples for HIV, HCV and HBV further reduces the risk of transfusion transmitted viral infections, as it uncovers the cases missed by currently used mandatory serological test.

Cost effective integration of NAT in blood screening strategy is the need of the hour as detection of the TTIs in window period not only prevents transfusion of infected blood / blood components, but also helps in early detection of infections preventing serious chronic complications, thus proving to be beneficial for both donors and recipients.

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