AN EXPERIENCE WITH ID-NAT AND IT'S ROLE TO REFINE BLOOD SAFETY AGAINST THE TRANSFUSION-TRANSMITTED INFECTIONS: A 3 YEAR RETROSPECTIVE STUDY

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ABSTRACT

Safety of blood is a daunting task, particularly in India, where HBV infection is highly prevalent (2-4%), HCV infection (2%) and HIV .infection (0.29%) among blood donors. The objective of this research is to assess the impact of donor nuclear acid testing (ID-NAT) on individuals in addition to Chemiluminescence. Immunoassay (ChLIA) on safety of blood transfusion currently in India. In order to assess the data from three years of extra NAT testing at Blood and Component Bank, J.N. Medical College and Hospital, AMU, Aligarh, a retrospective observational study was done. 2.11% (2431 of 115298) units were ID-NAT reactive while only 1.86% (2147 of 115298) units were reactive by ChLIA. A ID-NAT yield (NAT only reactive i.e sero-negative with ChLIA) of 0.25% (284 of 115298) was detected. 1 in 398 was the overall ID-NAT yield rate. In 3 years, ID-NAT testing prevented 284 probable .ID-NAT implementation for TTIs up to 1136 (assuming 100% component separation) and recipients of transfusions.in addition to Chemiluminescence Immunoassay (ChLIA) has improved the outcome in terms of safety of blood transfusion.

KEYWORDS: ID-NAT, Transfusion, Infection, Chemiluminescence Immunoassay (ChLIA)

INTRODUCTION

Indian has about 1.2 billion population, has around 43 million cases of HBV infection, around 15 million cases of HCV infection and around 2.5 million cases of HIV infection, which is much higher compared to developed countries (1).

Minimizing the Transfusion Transmitted Infections (TTI) risk along with ensuring safe blood supply is one of the major concern throughout the world. In spite of the present serological screening methods, transmission of viral antigen still occurs during window period.

Introduction of NAT in many centers decreases the risk of TTI throughout the window period. NAT was first introduced in Germany in 1997 on routine basis. Austria and Japan were first to implement mandatory NAT-HBV testing in 1999 (2).

ID-NAT can detect virus earlier than existing screening methods. It detects viral RNA and DNA amplification and decreases window period. ID-NAT can identify low level of viral genomic materials which are found in blood even before the body starts producing antibodies and hence allow for early identification of infection and reduces the possibility of TTI (3).

ID-NAT screening increases the sensitivity of overall screening for transfusion related viral transmission and improves transfusion safety, thus vetoing the TTIs that could be missed in serological screening, if done during window period (4).

For HIV detection with ID-NAT (Procleix Ultratron Elite Assay), the window duration is 4.7 days; for HCV infection detection, it is 2.2 days; and for HBV detection, it is 15 days (5-6).

The purpose of the current investigation is to assess the impact of individual donor nuclear testing (ID-NAT) in addition to chemical luminescence immunoassay (ChLIA) on the safety of blood transfusions that occur in India today.

MATERIALS .AND .METHOD

To assess the data over the course of three years (January 2019 to September 2021), an observational study was carried out retrospectively.by Individual Donor Nucleic Acid Amplification Test (ID-NAT) for HIV-RNA, HBV-DNA, and HCV-RNA. and Chemiluminescence Immunoassay (ChLIA) for HBV-Ag, anti-HCV, and anti-HIV at Blood and Component Bank, J.N. Medical College and Hospital, AMU, and Algarh.

The molecular TTI screening assay-ID-NAT (Procleix Ultron Elite Assay) utilizes the transcription-mediated amplification principle (TMA).

Procleix ID-NAT Testing Algorithm

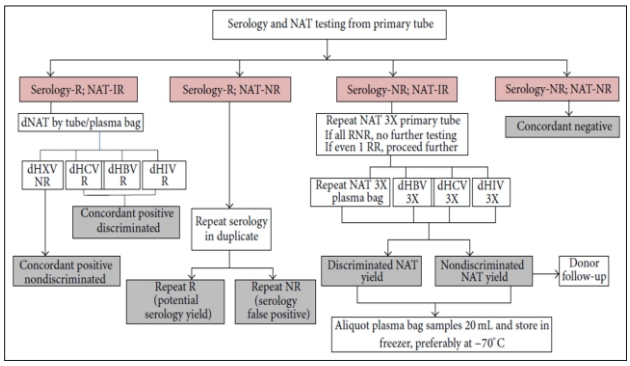

Fig. 1: Algorithm utilized for ID-NAT at Blood and Component Bank, J.N. Medical College and Hospital, AMU, and Aligarh

Chemiluminescence Immunoassay (ChLIA) is widely used and preferred in many blood banks .as .a routine .screening .test to prevent TTI. It is a highly sensitive method capable of producing luminescence during electrochemical reactions to measure the formation of the antigen-antibody complex.

ID-NAT was implemented on routine basis in addition to the ChLIA and then the NAT yield was calculated.

RESULTS

Over the course of the current trial, which will last three years. (January 2019 – September 2021), A total of 115298 donated blood units were collected in the Blood and Component Bank, and the blood units were then screened by both ID-NAT and ChLIA for HIV, HBV, and HCV. Table 1 below shows the donor status and gender stratification.

Total donations:	115298	
Gender	Males	111954 (97.1%)
	Females	3344 (2.9%)
Donor status	First times	107227 (93%)
	Repeat donors	8071 (7%)

Table 1: The stratification of gender and donor status

Out of total 115298 tested blood units, (66 0.06%) were reactive by ID-NAT while 63 (0.06%) were reactive by ChLIA for HIV Therefore ID-NAT yield (NAT only reactive i.e sero-negative with ChLIA) of 3 (0.003%) was obtained with ID-NAT yield rate of 1 in 38411 which has been described in Table 2.

Year	Units tested	ID-NAT Reactive	ChLIA Reactive	ID-NAT Yield	ID-NAT Yield Rate
2019	36251	21	21	0	0
2020	39326	25	24	1	1in 39301
2021	39721	20	18	2	1in 19851
Total	**115298**	**66 (0.06%)**	**63 (0.06%)**	**3 (0.003%)**	**1 in 38411**

Table 2: Year-wise Descriptive details of ID-NAT-Reactive cases for HIV

A ID-NAT yield of 241 (0.21%) was obtained for HBV with 1931 (1.67%) ID-NAT reactive blood units whereas 1690 (1.47%) blood units came out to be reactive by ChLIA providing us with ID-NAT yield of 241 (0.21%) and ID-NAT yield rate of 1 in 423 as mentioned in the Table 3.

Year	Units tested	ID-NAT Reactive	ChLIA Reactive	ID-NAT Yield	ID-NAT Yield Rate
2019	36251	785	683	102	1 in 348
2020	39326	680	608	72	1 in 537
2021(Upto September)	39721	466	399	67	1 in 586
Total	**115298**	**1931 (1.67%)**	**1690 (1.47%)**	**241 (0.21%)**	**1 in 470**

Table 3: Year-wise descriptive details of ID-NAT-Reactive cases for HBV

For HCV, a total of 343 (0.29%) blood units were reactive by ID-NAT. However ChLIA gave only 326 (0.28%) reactive blood units and thus ID-NAT yield came out to be of 17 (0.01%) with 1 in 6762 ID-NAT yield rate as shown in Table 4.

Year	Units tested	ID-NAT Reactive	ChLIA Reactive	ID-NAT Yield	ID-NAT Yield Rate
2019	36251	144	137	7	1 in 5158
2020	39326	133	128	5	1 in 7839
2021(Upto September)	39721	66	61	5	1 in 7932
Total	**115298**	**343 (0.29%)**	**326 (0.28%)**	**17 (0.01%)**	**1 in 6762**

Table 4: Year-wise descriptive details of ID-NAT-Reactive cases for HCV

95 (0.08%) co-infections were detected by ID-NAT as compared with ChLIA which detected 72 (0.06%) co-infections giving ID -NAT yield of 23 (0.02%) and 1 in 5009 as ID-NAT yield rate. Details are given below in Table 5.

Year	Units tested	ID-NAT Reactive	ChLIA Reactive	ID-NAT Yield	ID-NAT Yield Rate
2019	36251	9	8	1	1 in 36242
2020	39326	41	27	14	1 in 2806
2021(Upto September)	39721	45	37	8	1 in 4960
Total	**115298**	**95 (0.08%)**	**72 (0.06%)**	**23 (0.02%)**	**1 in 5009**

Table 5: Year-wise descriptive details of ID-NAT-Reactive cases for Co-infections

In total 2.11% (2431 of 115298) units were ID-NAT reactive while only 1.86% (2147 of 115298) units were reactive by ChLIA A ID-NAT yield of 284 (0.25%) was detected with an overall ID-NAT yield rate of one in 398 which has been summarised in Table 6.

Total Units tested	Total ID-NAT Reactive	Total ChLIA Reactive	Total ID-NAT Yield	Total ID-NAT Yield Rate
115298	**2431 (2.11%)**	**2147 (1.86%)**	**284 (0.25%)**	**1 in 398**

Table 6: Descriptive details of total NAT-Reactive cases (HIV, HBV, HCV and Co-infections)

DISCUSSION

Thorough screening for transfusion-associated infections (TTIs) in donated blood units is necessary to ensure a safe and cost-effective blood supply. The frequency of HBV, HCV, and HIV is high, and the window periods for these infections are lengthy. These facts make it a difficult situation for safety of blood supply (7). The above mentioned facts are expected to yield significant amount of donations during the window period. Therefore, NAT screening is introduced to detect more cases in donors of blood for transfusions and illnesses that are transferred in the form of NAT yield (8).

In present study, 115298 samples were tested by both ID-NAT and ChLIA 243 (2.11%) samples were ID-NAT-reactive, 2147 (1.86%) samples were ChLIA-reactive ID-NAT yield was 284 (0.25%) out of which highest ID-NAT yield was for HBV (241 .i.e .0.21%) followed by HCV (17 .i.e .0.01%) and HIV (3 .i.e 0.003%). The ID-NAT yield for co-infections was 23 (0.02%) 1 in 398 ID-. The NAT yield rate was given, and it is greater than 1 in 2622. NAT yield rate, as reported by Chatterjee et.al (9). Agarwal et .al stated 1 in 610 ID-NAT yield rate (8). This variability in yield rates of ID-NAT as compared to other study could be due to difference in sample size. The ID- The NAT yield rate of 1 in 398 is greater than in prior experiments conducted by different authors from various other countries (8, 10-11). The reason for these variations in the yield rate could be attributed to India's high prevalence of HBV, HCV, and HIV along with low voluntary donation rates when compared to replacement donation rates. The yield rate for HBV was 1 in 470, while the yield rate for HCV was 1 in 6762. For HIV and Co-infections, the yield rate for NAT was 1 in 38411 and 1 in 5009, respectively.

At our Blood and Component Bank, JNMC, AMU, the collected whole blood units are divided in four components (PRBCs, FFP, random donor platelets and cryoprecipitate), and therefore in this study about 1136 (284x4) instances of transfusion-transmitted infections were avoided by using ID-NAT in the course of the study duration itself, accomplished through technological advancements by the use of ID-NAT.

CONCLUSION

Screening of the blood that was donated by ID-NAT testing for the period of 3 years in our Blood and Component Bank, JNMC, AMU has amplified the sensitivity of screening for the exchange of viruses by blood transfusion.

The above mentioned data evaluation supports the benefit of using ID-NAT testing of the donated blood over ChLIA for improving blood transfusion safety. The key advantage is that the risk of transmission of virus has been reduced during the window periods. This would prevent the transmission of virus that could be missed on routine serological blood screening.

In less than three years from the start of our investigation, ID/NAT testing found 284 (0.25%) infections in donated blood units that the ChLIA had missed; this helped about 1136 blood transfusion users avoid TTIs. Blood banks should conduct routine, universal screening of blood components utilizing ID-NAT for TTIs in order to make blood donation safer.

In light of the significance of both ID-NAT and ChLIA in shortening the time window for virus detection, we recommend that ID-NAT be used regularly for blood screening in order to move closer to having our screening process meet international standards.

REFERENCES

1. Dodd RY, Notari EP, Stramer SL. Current prevalence and incidence of infectious disease markers and estimated window-period risk in the American Red Cross blood donor population. Transfusion. 2002; 42: 975-979.
2. Roth WK, Busch MP, Schuller A, et al: International survey on NAT testing of blood donations: expanding implementation and yield from 1999 to 2009. Vox Sang. 2012; 102: 82-90.
3. Chatterjee K, Coshic P, Borgohain M, et al. Individual donor nucleic acid testing for blood safety against HIV-1 and hepatitis B and C viruses in a tertiary care hospital. Natl Med J India. 2012; 25: 207-209.
4. Kabita C., Poonam C., Rahul R. et al. Five years of experience with ID-NAT at a tertiary care centre in North India: An interdictory step in preventing the transfusion-transmitted Infections. ISBT Science Series.2016; 11: 38-44.
5. Palla P, Vatteroni ML, Vacri L, et al. HIV-1 NAT minipool during the preseroconversion window period: Detection of a repeat blood donor. Vox Sang. 2006; 90: 59-62.
6. Weusten J, Vermeulen M, Van Drimmelen H, et al. Refinement of a viral transmission risk model for blood donations in seroconversion window phase screened by nucleic acid testing in different pool sizes and repeat test algorithms. Transfusion. 2011; 51: 203-215.
7. Chandrashekar S. Half a decade of mini-pool nucleic acid testing: cost-effective way for improving blood safety in India. Asian J Transfus Sci. 2014; 8: 35-38.
8. Agarwal N, Chatterjee K, Coshic P, et al. Nucleic acid testing for blood banks: an experience from a tertiary care centre in New Delhi, India. Transfus Apher Sci. 2013; 49: 482-484.
9. Chatterjee K, Coshic P, Borgohain M, et al.: Individual donor nucleic acid testing for blood safety against HIV-1 and hepatitis B and C viruses in a tertiary care hospital. Natl Med J India. 2012; 25: 207-209.
10. Vermeulen M, Lelie N, Sykes W, et al.: Impact of individual donation nucleic acid testing on risk of human immunodeficiency virus, hepatitis B virus, and hepatitis C virus transmission by blood transfusion in South Africa. Transfusion. 2009; 49: 1115-1125.
11. Nubling CM, Heiden M, Chudy M, et al. Experience of mandatory nucleic acid test (NAT) screening across all blood organizations in Germany: NAT yield versus breakthrough transmissions. Transfusion. 2009; 49: 1850–1858.

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