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Original Research Article

Bolstering blood safety: Revealing six years of vigilance-NAT testing trends in infectious markers among tertiary care centre blood donors

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Abstract

Background: Transfusion transmitted disease was a major risk factor for Blood Transfusion. TTIs (HBV, HCV, HIV, Syphilis, Malaria) screening by ELISA was done mandatory for screening of Blood donors. In order to provide additional layer of safety IDNAT was implemented nowadays in few blood centres to increase the safety of blood transfusion. Recent studies shown that TTIs Risk was high in developing Countries.
Aim and Objective: This study was done to study the seroprevalence of TTI and estimate the benefits of implementing IDNAT in blood Donor Screening.
Materials and Methods: In this study data collection was done around 6 years. This study included 11,641 blood donors during study period. Among the donors, 9876 (84%) volunteered, while 1765 (15%) were replacement donors.
Result: The TTI seropositivity rate stood at 0.98% (n=114), with a prevalence of 0.67% for HBV, 0.21% for HCV, 0.06% for HIV, 0.04% for Syphilis, and 0% for Malaria. The NAT yield for HBV was determined to be one, while the yields for HCV, HIV, Syphilis, and Malaria were also calculated and found to be Zero. Decreasing Trend of TTI was seen from 2016-2022.
Conclusions: Our study documented low Prevalence of TTIs, low participation of female donors and decreasing trend of TTIs. The recommendations include the Promotion of enrolment of female donors and screening of donated blood through highly sensitive screening method (IDNAT).

Keywords: Blood Donors, Seroprevalence, IDNAT, TTI, ELISA

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1. Introduction

Blood Transfusion is now integrated as part of Health Care System saving million lifes of people every year.[1] The prevention of Transfusion Transmitted Infections (TTIs) is essential to ensure safe blood transfusions, as these diseases can be transmitted from donor to recipient through blood transfusion. TTIs are caused by pathogens such as the Human Immunodeficiency Virus (HIV), Hepatitis B virus (HBV), Hepatitis C virus (HCV), syphilis, and malaria. To prevent TTIs, the National AIDS Control Organization (NACO) has mandated the screening of HIV, Hepatitis B, Hepatitis C, syphilis, and malaria on all donated blood. All blood units tested Positive for TTI should be discarded.[2] Screening can be done by ELISA and IDNAT technique.

Even after the mandatory screening procedure blood donation is not safety due to presence of blood donation during window period. Occult blood infection is not detected by routine serological test. In view of increasing blood safety Various Governments have introduced IDNAT for screening of TTIs. IDNAT facility was implemented in our Institution from 2020 and blood samples collected from donor units was sent for NAT screening at Gleenagles Global Hospital, Perumbakkam.

IDNAT is a highly sensitive molecular technique that can detect even lower level of viral genomic material which can't be detected by serological test.[3,4] In western countries Implementation of NAT has drastically reduced the risk of TTI. NAT was introduced in the late 1990s and early 2000s and Currently 33 countries have implemented NAT testing for HIV virus and 27 countries for Hepatitis B virus.[5] NAT

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has reduced the window period of HIV to 2.93 days, HBV to 10.34 days and HCV to 1.34 days.[6] Two types of NAT-Minipool and Individual are present. ID-NAT seems to be more sensitive than MP-NAT.[7,8]

Based on this data, we have decided to estimate the seroprevalence of infectious markers among blood donors and to analyze their yearly trends over a six-year period. Additionally, we aim to evaluate the safety benefits of implementing Individual Donor Nucleic Acid Testing (IDNAT) in the screening of blood donors.

2. Materials and Methods

2.1. Study design

Retrospective study.

A thorough retrospective examination was conducted on TTIs reactive units screened through ELISA at a tertiary care hospital, spanning a comprehensive six-year period from January 2016 to January 2022. The data was collected from the blood bank records. All the units were tested for HIV, HBV, HCV by ELISA. The test for syphilis was done by Rapid Plasma Reagin method and Malaria by card test. Utilizing blood bank records, a retrospective analysis was undertaken to evaluate the prevalence and trends of Transfusion Transmissible Infections (TTIs) over a span of two years, from February 2020 to February 2022. Additionally, the NAT yield was calculated to assess the efficacy of this screening method in detecting TTIs.

2.2. Study setting

Blood bank, Chettinad Hospital And Research Institute, Chengalpet.

2.3. Statistical methods

The results obtained was analysed for statistics using SPSS Software version 22.0.

p value was calculated wherever necessary using student 't' test.

3. Results

During our study period (2016- 2022) we received 11,641 blood units from donors. Age group of donors was ranging from 18-65 years with mean age of 25years. The gender proportion among the cases was determined to be predominantly male, accounting for 97% of the cases, while females represented 3% of the cases. Figure 1 illustrates the distribution of Transfusion Transmissible Infections (TTIs) seropositivity rates over a six-year period. During this time frame, the seropositivity rate for TTIs was found to be 0.97%, with a total of 114 cases identified. Seropositivity rate of TTIs was more common among the age group 18-35 yrs (**Figure 2**). In our study Hepatitis B virus infection was the common Transfusion Transmitted Infection found during screening followed by Hepatitis C. TTI are more commonly found among O positive blood donors followed by B Positive donors (**Figure 3**).

Voluntary donors (82.6%) found to carry the highest risk of TTI than replacement donor (17.4%) in our study. Seropositivity rate of TTIs was more common among Male donors (114).Yearly trend of seroprevalence of TTIs was explained in (**Figure 4**, **Figure 5**).

Table 1: Comparison of TTI prevalence in voluntary and replacement blood donors

Donation Category	HIV	HBV	HCV	VDRL	Total
Voluntary	7(0.070%)	61(0.617%)	23(0.232%)	4(0.040%)	95(0.96%)
Replacement	0	16(0.90%)	2(0.11%)	1(0.0058%)	19(1.07%)
Total	7(0.06%)	77(0.66%)	25(0.17%)	5(0.04%)	114(0.97%)

Table 2: Comparison of IDNAT with ELISA

Year	No of samples tested	Seropositive/ Nat positive cases	Seronegative / Nat positive cases	Seropositive/ Nat negative cases
2020-21	1260	15	1	1
2021-22	1537	14	0	2

Table 3: Year-wise infected cases of HBV, HCV, HIV, and VDRL

Year	Total screened	HIV	HBV	HCV	VDRL	Total
2016 – 2017	1883	0	7(0.37%)	2(0.10%)	0	9(0.47%)
2017 – 2018	2161	4(0.18%)	7(0.32%)	3(0.13%)	0	14(0.64%)
2018 – 2019	2247	3(0.13%)	16(0.71%)	6(0.26%)	0	25(1.11%)
2019 – 2020	2279	0	13(0.57%)	11(0.48%)	2(0.52%)	26(1.14%)
2020 – 2021	1541	0	20(1.29%)	1(0.06%)	1(0.06%)	22(1.42%)
2021 – 2022	1530	0	14(0.91%)	2(0.13%)	2(0.13%)	18(1.17%)

Table 4: Chi–square test year wise infected cases of TTI

	Value	Df	Asymp. sig(2 sided)
Person Chi - Square	35.119[a]	15	.002
Likelihood Ratio	35.997	15	.002
Linear by – linear association	.569	1	.451
No of Valid cases	114		

There is increasing trend of VDRL and decreasing trend of HIV, Hepatitis C virus, Hepatitis B virus,

The prevalence of VDRL, HBV, HCV, HIV among voluntary blood donor was 0.040% (n = 4) 0.070% (n= 7), 0.61% (n = 61), 0.23% (n = 23), and 0.070% (n= 7) respectively, whereas in replacement blood donors it was 0.05% (n = 1), 0.90% (n = 16), 0.11% (n=2), and 0% (n = 0) respectively. The TTIs prevalence rate among blood donors (voluntary and replacement) was given in (**Table 1**).

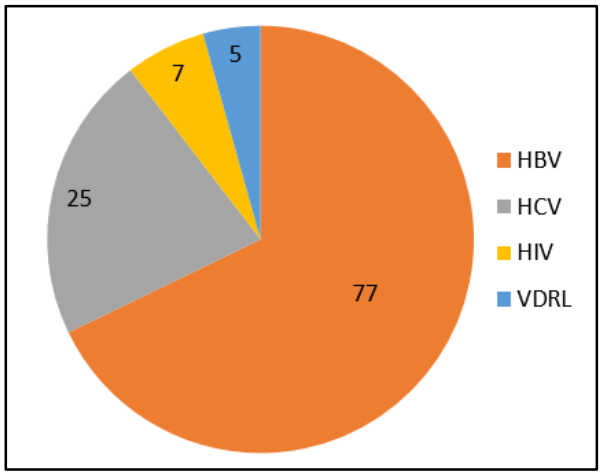

Figure 1: Seropostivity rate of TTI

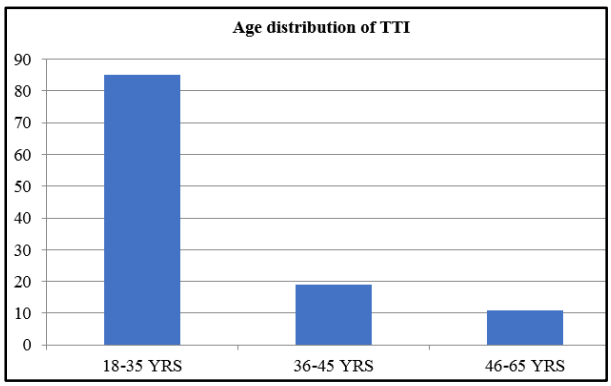

Figure 2: Age distribution of TTI

Over the period of two years (2020-2022) 2797 blood donors underwent screening for TTIs by both ELISA and IDNAT. Among them 28 were reactive for Hepatitis B infection by both ELISA and IDNAT, 1 were reactive for Hepatitis C infection by both ELISA and IDNAT. Seropositive/NAT negative cases were 2 for Hepatitis C infection and 1 for Hepatitis B infection. NAT yield was 1 for Hepatitis B and zero for Hepatitis C, HIV, VDRL in our study.(**Table 2**)

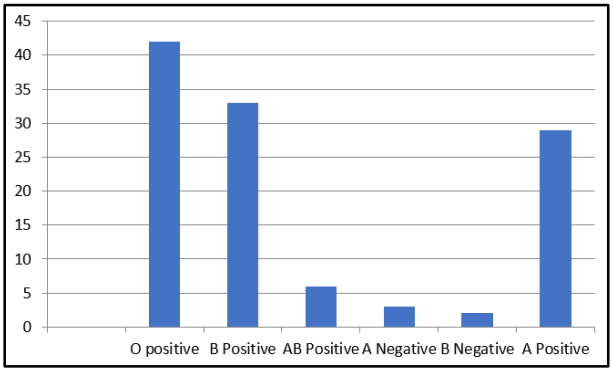

Figure 3: Distribution of TTI among various blood groups.

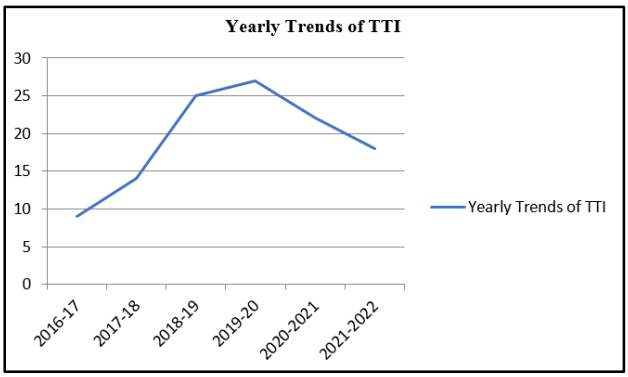

Figure 4: Yearly trends of TTI

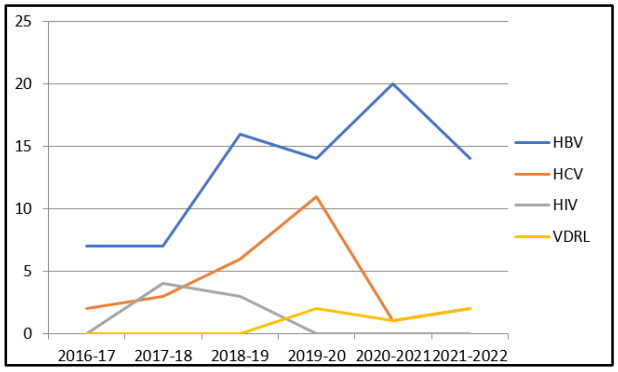

Figure 5: Year wise specific trends of TTI

Based on the chi-square table provided, with a chi-square value of 35.119 and a significant value of 0.002, it can be concluded that there is a significant relationship between the test and the year.

4. Discussion

Blood transfusion is a life-saving procedure saving lives of countless patients worldwide. Blood transfusion plays an important role in the transfusion of infectious agents. The rate of transmission of transfusion transmitted disease from every blood unit transfusion is approximately 1%.[9]Some of these infections are severe life threatening disease that have difficult treatment or incurable.

During our study period we received 11,641 blood units which was low compared to other previous studies. Age group of donors was ranging from 18-65yrs with mean age of 25yrs which is similar to study done by Rohit jain et al.[10] Female participation in blood donation is very low in our study. This may be attributed to the fact of lack of knowledge about blood donation and poor health status. Proper counselling and awareness can improve the enrolment of female donors.

In our study Hepatitis B virus infection was the common Transfusion Transmitted Infection found during screening followed by Hepatitis C. There is decreasing trend of Hepatitis B virus, Hepatitis C virus, HIV, VDRL. No cases of Malaria reported. Overall decreasing trend of TTI was observed in our study. This finding was similar to study done by Soumya T.S et al.(**Table 3**, **Table 4**).[11]

The declining trend observed in Hepatitis B infections could be attributed to the widespread administration of the Hepatitis B vaccine across India. Similarly, the decreasing trends noted in VDRL, Hepatitis C and HIV infections may be due to the stringent screening protocols implemented before every surgical procedure and during donor screening.

The incidence rate of HIV, HBV, HCV, and VDRL among voluntary blood donor was 0.070% (n= 7), 0.61% (n = 61), 0.23% (n = 23), and 0.040% (n = 4) respectively, whereas in replacement blood donors it was 0%(n = 0),0.90% (n = 16), 0.11% (n=2),and 0.05% (n = 1), respectively.

Therefore our prevalence rate is lower than the result from Karachi, Islamabad , Faisalabad, Nigeria and Albania where they reported seroprevalence 5.8%,[11] 14.34%,[12] 6.55%,[13] 14.96%,[14] 7.4% respectively.[15]

*The overall prevalence of HIV in the present study was 0.06% this percentage is significantly higher when compared with earlier studies which have reported a prevalence rate of 0.02%,[15] 0.04%.[11]

*The overall prevalence of hepatitis B in our study was 0.66% this was lower when compared with some local studies which displayed 1.84%[11] and 1.29%.[16] This finding may indicate the likelihood that the prevalence of HBV in the general population is relatively high. Our findings were on the lower side when compared from other local studies

Among 2797 donor screening, 3 donors tested positive for TTI by ELISA but negative by ID-NAT, these false positive reactions can be explained due to high sensitivity of ELISA. Therefore we recommend follow up and further testing for confirmation.

The NAT yield for Hepatitis B was determined to be one .The yield in our study was similar to yields obtained in previous Indian studies like AIIMS[17] -1:2622, Jaipur[18] - 1:2972 and Andhra Pradesh[19] -1:2000 Our yield was less compared to an yield in Apollo-1:686, New Delhi,[20] another study in AIIMS[21] -1: 476 and RML hospital in Delhi - 1:1125 and much higher compared to an yield of Medanta -1:4403 , Rotary TTK[22]-1:5000 , Manipal Hospital[23]-1:17753

Several factors contribute to the variation in NAT yield across different studies and locations. These include the type of test utilized, the specific kit employed, the sensitivity and accuracy of the test, as well as the frequency of infection among donors. NAT yield in developed countries was lower than developing countries which is due to the high prevalence of TTI in developing countries.

Comparison of NAT yield in our study with other previous studies is listed below.

Table 5:

Studies	Nat yield
Chatterjee K, Coshic P et a[l17]	1 in 2622
Chandra T, Rizvi FN et al[25]	1 in 156
Kumar R, Gupta S et al[24]	1 in 753
Chaurasia R, Zaman S et al[26]	1 in 628
Agarwal N, Chatterjee K et al[27]	1 in 650
Jain R, Aggarwal P et al[12]	1 in 2972
Makroo RN, Choudhary N et al[20]	1 in 1528
Present Study	1 in 2797

5. Conclusion

The present study showed low prevalence of TTIs in South India compared to other parts of India. Six year period of this study showed decreasing trend in Seroprevalence of HBV, HCV, HIV, VDRL, Syphilis and Malaria. Strict donor screening plays an important role in prevention of Transfusion Transmitted Disease. The results in the present study suggest that implementation of NAT would provide an additional layer of safety to ensure safe blood transfusion.

6. Ethical Committee

Ethical Committee approval was obtained from Chettinad Academy of Research and Education Institutional Human ethical committee. Approval no. IHEC-I/0389/21.

7. Consent to Participate

Not applicable.

8. Source of Funding

No source of Funding.

9. Conflict of Interest

None.

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