

Seroprevalence of transfusion-transmissible infectious agents (HIV, HBV, HCV, plasmodium species and treponema pallidum infections) among blood donors at a Tertiary Care Teaching Hospital in Chennai: Changing trends over a period of five years

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Abstract

Introduction: Transfusion-transmissible infections (TTI) are principal threat to the recipient of a blood transfusion. Consequently, Drugs and cosmetics act asserts that mandatory screening tests must be performed to rule out TTI (human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), Plasmodium species and Treponema pallidum). The principal intention of this study was to resolve the seroprevalence and inclining trends of TTI amongst blood donors at a tertiary care teaching hospital in Chennai.

Materials & Methods: A detailed retrospective study and analysis of successive blood donors (both voluntary and replacement) records covering over the period from January 2010 and December 2014 was carried out. Statistical analysis was performed to establish the trends interconnected with TTI.

Results: 2006 (1.2%) donor blood samples from 165809 successive blood donors were tested to be serologically reactive for at least one infectious agent, amongst which 14(0.008%) samples tested contained more than one TTI agents. Correspondingly, on the whole seroprevalence of TTI agents - HIV, HBV, HCV, Plasmodium sp. and Treponema pallidum infections was 0.04%, 1.14%, 0.022%, 0.0006 and 0.0006%. A statistical significant correlation was identified between HBV and HIV viral infections. Furthermore, appreciably declining tendency in seropositivity of HIV, Plasmodium sp. and Treponema infections and continuing increasing drift of perilous HBV and HCV sero-reactivity was identified throughout the study phase.

Conclusion: A considerably significant fraction pool of blood donations spread HIV, HBV and HCV infections. Compulsory screening of donors' blood with stringent selection of voluntary blood donors along with by prescribed standard techniques are particularly recommended to guarantee the protection of recipient undergoing blood transfusion.

Keywords: Drugs and cosmetics act 1940, Mandatory screening test, Seroprevalence, Transfusion-Transmissible Infectious (TTI) Agents.

Introduction

Blood banking services form an indispensable part of the Health Services in a nation. With increasing demand for blood products associated with increasing Transfusion-transmissible infections (TTI) amid remarkable progress in transfusion technology had made regularising agencies to make obligatory regulations to assure safe, potent, effective and quality blood components for the recipient. Director General of Health Services along with Drugs Controller General of India carried out amendments with modifications periodically in the Drugs and Cosmetic Act, 1940 to warranty quality assurance systems for better and safe blood transfusion services.¹

Transfusion of blood products even though beneficial to the patient has its own hazards. The most dangerous risk is the TTI.² The mandatory screening for TTIs on blood donors have started a bright future for health services thereby providing safe transfusion.^{1,3,4}

As per Drugs and cosmetics act³, the mandatory screening tests on donated blood units in India are:

1. Surface antigen of *Hepatitis B virus*
2. Screen for antibodies to glycoprotein of *HIV-1* & 2

3. Antibodies against *Hepatitis C virus* (Anti HCV)
4. Antibody to *Treponema pallidum* (Syphilis), and
5. *Malarial organism*

There is always a question related to the safety associated with blood transfusion in India where adequate financial resources, trained personnel, good infrastructure along with the best national blood policy is present but the blood transfusion services are not vigilantly monitored as hemovigilance programme of India is in the initial stages of implementation.⁵

Among the Asian countries, a well established hemovigilance system is lacking and there is paucity of data on hemovigilance except for Japan, which has published report on adverse transfusion reactions and infectious diseases.^{6,7}

Viral infections such as HIV, HBV and HCV cause big anxiety due to protracted viraemia along with carrier / latent state. Transfusion of blood components contribute up to 1% to the HIV transmission among the individuals in India.⁸ Due to the currently prevalent stringent screening practices, the percentage of HIV cases attributable to blood transfusion has decreased considerably from 8% in mid-nineties to 1% in 2009.⁹

Hepatitis is one of the public health hazards worldwide today.^{10,11} A study by Patwari et al reported higher incidence of *HBV*-carrier state in transfusion recipients as compared to the general population (12.3% vs. 3.6%) and found the incidence of TAH-B (transfusion associated *hepatitis B*) to be 11%.¹² Likewise, 12.3% of patients are at risk of post transfusion hepatitis due to blood transfusion.¹³

Hepatitis C virus can cause post-transfusion liver inflammation and injury.^{1,6} Till date, there is no preventable vaccine for *HCV* virus, and also drug treatment and interferon therapy for *HCV* infection is expensive.^{11,12}

Treponema pallidum can spread through blood component transfusion even though Syphilis can also spread by sexual actions and by means of vertical transmission.^{14,15} *T.pallidum* can be transmitted by fresh blood and in exchange transfusion of blood in newborns. It is not transmitted by plasma products fractionated from pooled plasma such as Factor VIII. It is usually not transmitted by stored blood as refrigeration at 4°C inactivates the organism within 72 hours.¹

Malaria transmitted through blood Transfusion (TTM) is most commonly caused by *P. falciparum* followed by *P. vivax* and *P. malaria*. Transmission of malaria has been reported to occur mainly from whole blood and from packed red blood cell concentrate.¹⁶⁻²¹

The seroprevalence of TTI in blood donor population has raised the troubles associated with protection of blood product transfusion in India. Hence, there is a need for uninterrupted inspection of TTI in blood donors to estimate the perils of blood component transfusion. Based on the above criteria, the present study was carried on to resolve and establish the seroprevalence and ongoing trends of TTI (*HIV*, *HBV*, *HCV*, *malaria* and *syphilis*) amid blood donors at a tertiary care medical college teaching hospital in Chennai.

Materials and Methods

A detailed retrospective analysis of successive voluntary and replacement blood donors' records over the period from January 2010 and December 2014 was conducted at a tertiary care medical college teaching hospital in Chennai. The group of blood donors was either voluntary blood donors, or replacement donors (friends/relations of recipients'). TANSACS self questionnaire was filled by Potential blood donors. NACO criteria were used to screen the blood donors. The details of the donor were filled in the donor logbook. After taking sterile precautions, venous phlebotomy was performed and blood was collected in sterile blood collection bags. ABO Blood grouping and Rh typing was performed on all donors.

Laboratory diagnostic tests for identifying antibodies to glycoprotein of HIV 1 & 2: NACO supplied ELISA kit with reported sensitivity & specificity of 100% & 99.34% respectively were used in identifying antibodies to glycoprotein of *HIV 1&2* in donor's serum/plasma.

Screening kit tests for HBsAg and antibodies to HCV (NACO supplied kit): ELISA kit with reported sensitivity & specificity of 100% & 99.9% respectively were used in identifying *hepatitis B* surface antigen in donor's serum/plasma. Likewise, antibodies to *HCV* antigens for core, NS3, NS4 and NS5 were detected using ELISA technique with reported sensitivity of 100% and specificity of 99.02%.

All serologically reactive and grey zone samples were tested again using the same ELISA kit as well as a rapid test kit based on the principle of a one-step immunoassay. Samples showing repeat test reactivity on both methods were considered positive and were included for calculation of seroprevalence.

Laboratory diagnosis for *Treponema pallidum* (syphilis): Rapid plasma reagin test (RPR Test kit) was used to find for the existence of regain (IgM and IgG) antibodies in donor's serum/plasma.

Laboratory tests for *Plasmodium Species* (Malaria): Blood samples were tested for *malarial parasites* by blood smear (thick smear and thin smear).

Statistical analysis

Information was collected in a structured proforma. Data was entered in MS Office Excel format. SPSS software (version 20) was used for statistical analysis of the collected variables. Variation in the seroprevalence of TTI and Socio-demographic variables were investigated for significance using logistic regression. Linear regression was performed to evaluate the statistical significance of trends in seroprevalence of these TTI agents over the study period.

Results

165809 successive blood donors were screened at the blood bank of a medical college teaching hospital throughout the study period. Table no.1 shows the socio—demographic characteristics of blood donors and Table 2 shows the prevalence of blood donors according to blood groups. Among the study group, 92712 (55.91%) were in the age group of 18-25 years, 104459 (62.99%) were first time blood donors, 64997 (39.19%) were O blood group and 154497 (93.18%) were Rhesus D (Rh) positive donors. In addition, College/University students (32.2%), corporate company staff (31.7%) and daily laborers (23.3%) constituted a major portion of the blood donors.

Seroprevalence of TTI

In general, the seroprevalence rate of TTI- *HIV*, *HBV*, *HCV*, *Plasmodium species* and *Treponema pallidum* was 0.04%, 1.14%, 0.022%, 0.0006% and 0.0006% respectively as shown in Table no.3. 2006 (1.2%) donor blood samples from 165809 successive blood donors were tested to be serologically reactive for at least one infectious agent, amongst which 14 (0.008%) samples tested contained more than one TTI agents. The most frequent combinations amongst the donors with multiple TTI infections were *HIV- HBV* (42.85%) followed by *HCV – HBV* (28.58%), *HIV-HCV* (21.43%) and *HIV-Syphilis* (7.14%) which are shown in Table 4. The seroprevalence of *HIV virus* was greatly increased amongst male blood donors in comparison to female blood donors, first time donors in comparison to repeat donors, and drivers and construction workers in comparison to students as shown in Table 5, but all the above comparisons were not statistically significant ($p > 0.05$). The seroprevalence of *HCV* was seriously increased amid daily laborers and construction workers in comparison to students but the above was not statistically significant. Statistical significant ($P < 0.05$) increase in seroreactivity of *HBV*

was seen amongst donors with the age groups 36 – 45 years and more than 45 years in comparison to the age group 26-35 years, daily laborers in comparison to students and first time donors in comparison to repeat donors.

Trends of TTI Seroprevalence

There was a notable significant waning trend of *HIV* ($P = 0.038$) during the phase of study. Seroprevalence of *HIV* virus which was recorded as 0.08% in 2010 decreased gradually to 0.02% in 2014. The seroprevalence of *HBV* virus which was recorded as 1.27% in 2010 had increased to 1.49% in 2013 and gradually decreased to 1.39% in 2014. *HCV* prevalence which was recorded as 0.012% in 2010 had progressively increased to 0.044% in 2013 and gradually decreased to 0.014% in 2014. The trend in *HBV* ($p=0.063$) and *HCV* ($p=0.059$) infection in donors was on a gradual increasing trend but the decrease in number of donors with *HBV* and *HCV* viral infection in 2014 was not statistically significant. There was only one donor with *Plasmodium infection* and *Treponema pallidum* infection each which could not be statistically evaluated for trend and drift.

Table 1: Socio—demographic characteristics of blood donors at a tertiary care teaching hospital in Chennai from January 2010 and December 2014

Characteristics	Number (No.)	Percentage (%)
<i>Age group(yrs)</i>		
18-25	92712	55.91
26-35	49793	30.03
36-45	14712	8.87
46-55	8114	4.89
56-65	478	0.29
<i>Gender</i>		
Male	130962	78.98
Female	34847	21.02
<i>Occupation</i>		
College Student	53391	32.2
Corporate staff	52562	31.7
Daily laborer	38634	23.3
Housewife	1493	0.9
Govt employee	4313	2.6
Merchant	6964	4.2
Defence and police personnel	2483	1.5
Driver	1989	1.2
Construction workers	3151	1.9
Others	829	0.5
<i>No. of donation</i>		
First donation	104459	62.99
Repeat donation	61350	37.0

Table 2: Prevalence of Blood donors according to blood groups

ABO Blood groups	Number (No.)	Percentage (%)
O	64997	39.19
A	35157	21.20
B	53721	32.39
AB	11927	7.19
Oh (Bombay group)	7	0.004
<i>Rhesus (Rh) type</i>		
Positive	154497	93.18
Negative	11312	6.82

Table 3: Changing Trends of seropositivity of TTI amongst blood donors at a tertiary care teaching hospital in Chennai from January 2010 and December 2014

Year	2010	2011	2012	2013	2014	Total	p-value of linear regression for trend
Total blood donors	32069	34413	31781	33656	33890	165809	
HIV (No.)	26	7	19	8	7	67	
HIV (%)	0.080	0.020	0.059	0.023	0.020	0.04	0.038
HBV (No.)	407	59	461	502	471	1900	
HBV (%)	1.27	0.17	1.45	1.49	1.39	1.14	0.063
HCV (No.)	4	1	12	15	5	37	
HCV (%)	0.012	0.003	0.037	0.044	0.014	0.022	0.059
Plas.Sps.(No.)	0	1	0	0	0	1	
Plas.Sps.(%)	0	0.003	0	0	0	0.006	-----
Trep.pal (No.)	0	0	0	1	0	1	
Trep.pal. (%)	0	0	0	0.003	0	0.006	-----

P < 0.05 is significant for declining drift & trend

Table 4: Prevalence of co-infections of TTI amongst blood donors at a tertiary care medical college teaching hospital in Chennai from January 2010 and December 2014

Co-Infections (TTI agents)	Number (No.)	Percentage (%)
HIV-Syphilis	1	7.14
HIV-HBV	6	42.85
HIV-HCV	3	21.43
HBV- Syphilis	0	0
HBV-HCV	4	28.58
Syphilis-HCV	0	0
Total	14	100

Table 5: Socio-demographic characteristics of blood donors by HIV, HBV & HCV sero positivity at a tertiary care teaching hospital in Chennai from January 2010 and December 2014

Characteristics	HIV reactive (n=67)	P - value	HBV reactive (n=1900)	P - value	HCV reactive (n=37)	P - value
<i>Age group(yrs)</i>	N (%)		N (%)		N (%)	
18-25	1/92712 (0.001%)	>0.05	36/92712 (0.038%)	>0.05	3/92712 (0.003%)	>0.05
26-35	23/49793 (0.058%)	>0.05	319/49793 (0.64%)	>0.05	18/49793 (0.036%)	>0.05
36-45	31/14712 (0.21%)	>0.05	1271/14712 (8.63%)	<0.05	12/14712 (0.08%)	>0.05
>45	12/8592 (0.139%)	>0.05	274/8592 (3.1%)	<0.05	4/8592 (0.046%)	>0.05
<i>Gender</i>						
Male	67/130962 (0.05%)	>0.05	1896/130962	<0.05	36/130962	>0.05

			(1.45%)		(0.027%)	
Female	0/34847 (0%)	---	4/34847 (0.011%)	>0.05	1/34847 (0.002%)	>0.05
<i>Occupation</i>						
Student	0/53391 (0%)	---	2/53391 (0.003%)	>0.05	1/53391 (0.001%)	>0.05
Corporate staff	1/52562 (0.001%)	>0.05	529/52562 (1.01%)	>0.05	2/52562 (0.003%)	>0.05
Daily laborer	42/38634 (0.11%)	>0.05	1174/38634 (3.04%)	<0.05	19/38634 (0.49%)	>0.05
Housewife	0/1493 (0%)	---	1/1493 (0.067%)	>0.05	0/1493 (0%)	---
Govt employee	0/4313 (0%)	---	2/4313 (0.046%)	>0.05	0/4313 (0%)	---
Merchant	1/6964 (0.01%)	>0.05	17/6964 (0.24%)	>0.05	3/6964 (0.04%)	>0.05
Defence and police personnel	0/2483 (0%)	---	0/2483 (0%)	>0.05	0/2483 (0%)	---
Driver	7/1989 (0.35%)	>0.05	61/1989 (3.06%)	<0.05	5/1989 (0.25%)	>0.05
Construction workers	16/3151 (0.5%)	>0.05	114/3151 (3.61%)	<0.05	7/3151 (0.22%)	>0.05
<i>No. of donation</i>						
First donation	51/104459 (0.048%)	>0.05	1706/104459 (1.63%)	<0.05	19/104459 (0.018%)	>0.05
Repeat donation	16/61350 (0.026%)	>0.05	194/61350 (0.31%)	>0.05	18/61350 (0.029%)	>0.05

P < 0.05 is significant association between parameters

Discussion

Notable and significant waning drift of *HIV* viral seroprevalence were observed in the phase of the study amongst blood donors in the present study. This finding is consistent with the noted declining trend and drift of *HIV* seroprevalence in the general population in India⁸ and waning trend of *HIV* prevalence amongst blood donors in India.²²⁻²⁸

HIV and *HBV* virus seroreactivity rate was significantly increased amongst first time donors in comparison to repeat blood donors in our study. This is in conformity with the previous studies.²⁸⁻³³ A significantly higher *HbsAg* seroprevalence was also reported in males than in females in the present study which is in consensus with other studies.^{29,34} There was higher prevalence of *HbsAg* donors in older than 35 years age group in the study group which was similar to studies by Rodenas et al.,³⁵ Baba et al.³⁶ and Ejele et al.³⁷ This observation is bothersome as the most fruitful and economically viable age group of the community is affected. There is a necessity for improved amplification of preventive agenda expected at high risk behavioral change.²⁹

In our study, the seroprevalence rate of *HCV* (0.022%) was in concurrence with the rates ranging between 0 and 1.4% in the studies conducted in USA³⁸

and Europe.³⁹ Nevertheless, it is lower than in the studies conducted in Ghana (2.8%) and Port Harcourt (2.9%).^{40, 41} The worldwide seroprevalence of *HCV* among blood donors varies from 0.4% to 19.2%.⁴²

Similarly, the Seroprevalence of *T.pallidum* (0.006%) in the present study is lower than the prevalence of 1.3% in Ethiopia³³ and 3.6% in Maiduguri.⁴³ In our study, none of the blood donors showed the existence of three or four TTI markers. Amid the blood donors with multiple infections, the *HIV – HBV* co-infection donor rate was 6/14 (42.85%), the *HIV – syphilis* co-infection was 1/14 (7.14%), the *HBV – HCV* co-infection was 4/14 (28.58%) and *HIV – HCV* co-infection was 3/14 (21.43%). This finding was comparable to the study conducted by Tessema et al.³³ and study published by Ejele et al.³⁷ This high rate of TTI co-infection and the statistically significant relationship between *HIV & HBV*, *HIV & syphilis*, *HBV & HCV* and *HIV & HCV* infections may be due to the fact that these infectious agents share the common modes of transmission and risk groups.^{33, 36, 37}

In the last decade, the sensitivity & specificity of TTI screening tests had increased; thereby the viral infection transmission through blood products has been nearly eliminated in developed countries and has decreased in developing countries.

Conclusion

A considerable proportion of the voluntary blood donors harbor transfusion-transmissible (TTI) infections. No vaccine exists to prevent TTI except HBV infection, and treatment for HIV & HCV infection is costly. Sero-reactively negative window period of an infectious agent is still a hindrance to safe blood transfusion. Even the latest Nucleic acid amplification testing has its own pitfalls; therefore ensuring 100% voluntary blood donation with the time tested protocol of pre-donation counseling of probable blood donors with complete screening of donors' blood for TTI using prescribed standard methods are highly recommended to ensure the safety of blood for recipient. Periodic studies to investigate transfusion-transmissible infectious diseases along with emerging and re-emerging infections are required to enable safe blood transfusion.

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