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Trends in the Prevalence of Transfusion Transmissible Infections in Blood Donors of Punjab: A Retrospective Analysis of Seven Years

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ABSTRACT

Background: Transfusion of blood components may be associated with the risk of Transfusion Transmissible Infections (TTIs). Blood is screened for Human Immunodeficiency virus (HIV), Hepatitis B virus (HBV), Hepatitis C virus (HCV), syphilis and malaria. This study was undertaken to demonstrate the trends in seroprevalence of TTIs in blood/platelet donors from April 2016 to December 2023.

Methods: Blood was screened for HIV, HBV, HCV with Enzyme Linked Immunosorbent Essay or Electro-Chemiluminescence or rapid test methods. Rapid tests were used for screening syphilis and malaria. The prevalence of individual TTIs was calculated and changes in trends were recorded. In addition, sero-reactive donors were categorized concerning age, educational status and rural-urban background.

Results: A total of 46,304 blood donors were screened for TTIs. The overall seroprevalence of TTIs was 2.05%. The order of prevalence was HCV (1.02%) > HBV (0.54%) > Syphilis (0.41%) > HIV (0.09%) > Malaria (0%). TTI prevalence increased from 1.46% in 2016 to 1.8% in 2023. Most of the sero-reactive donors (44.4%) belonged to the age group of 21-30 years and there was an inverse relation of level of education with seroprevalence. Majority (71%) of the sero-reactive donors had a rural background.

Conclusion: Blood/blood components must be as safe as possible. This can be achieved by recruiting and retaining voluntary non-renumerated donors and promoting awareness about the importance of safe practices. In addition, the adoption of more stringent pre and post donation screening protocols would help in ensuring a safe blood supply.

Key-words: Blood Donors, HBV, HCV, HIV, Syphilis, TTI Prevalence, TTI Trends

INTRODUCTION

Blood transfusion services (BTS) are an important and crucial part of any healthcare facility. Transfusion of blood or blood components is required for patients with massive trauma, obstetric complications, anemias, and also patients with hemoglobinopathies / coagulopathies, who are solely dependent on transfusion services.

Transfusion of blood/blood components may be associated with many complications, including the risk of transfusion-transmissible infections (TTIs). Human Immunodeficiency virus (HIV), Hepatitis B virus (HBV), Hepatitis C virus (HCV), syphilis and malaria account for the most common TTIs [1]. In India, the testing of every unit of donated blood was made mandatory for markers of HIV, HBV, Malaria and Syphilis under the Drug and Cosmetics Act (1st amendment) Rules 1992 [3]. Later, in June 2001, testing for HCV was also made mandatory [2]. To ensure the availability of safe blood/blood components for patients, many noteworthy advancements have been made in the field of Transfusion Medicine. However, the risk of TTIs is still

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one of the biggest challenges for transfusion services worldwide. This study was undertaken to demonstrate the trends in seroprevalence of TTIs in donors who donated blood/apheresis platelets with our blood centre over seven years (2016-2023). It was also intended to observe any noticeable changes in the trends of these TTI during this period and to determine whether gender, age, educational status or rural-urban background has any correlation with sero-reactivity.

MATERIALS AND METHODS

Place of study- This was a retrospective study carried out at Life Line Blood Centre, Patiala, which is a charitable blood centre in Punjab, India. The study included a total of 46,304 donors who donated whole blood/single donor platelets at our blood centre for seven years between April 2016 and December 2023.

Inclusion criteria- The study involved healthy whole blood/plateletpheresis donors. All the blood donors, satisfied the selection criteria, as laid out in the Drug and Cosmetic Rules, 1940 and Rules, 1945 and amendments thereafter.

Exclusion criteria- All the donors who did not meet the donor selection criteria were deferred from donating blood/platelets.

Data Collection- All the relevant information regarding blood donors including demographic data, weight, hemoglobin status and results of serological tests, was recorded and maintained by the blood centre, as per the standard operating procedures. Data for the present study was retrieved from donor records and it was entered in Microsoft Office Excel worksheets (Microsoft® Excel® 2021 MSO, Version 2409).

Testing Methodology- Blood was screened for HIV, HBV, HCV, syphilis and malaria. Testing for HIV, HCV and HBV was done mostly with the Enzyme-Linked Immunosorbent Essay (ELISA) or Electro-Chemiluminescence (E-CLIA) method. However, in some situations, like life-saving emergencies when freshly collected blood/apheresis platelets were being issued, rapid tests were employed due to paucity of time. Tests were performed on pilot tube blood samples collected in EDTA vacutainers, at the time of blood/platelet donation.

ELISA tests were performed using 4th generation HIV kits (4th Generation Microlisa HIV Ag & Ab, J. Mitra & Co. Pvt. Ltd., India), 3rd generation HCV kits (HCV Microlisa, J. Mitra & Co. Pvt. Ltd., India) and HBV kits (Hepalisa, J. Mitra & Co. Pvt. Ltd., India), from April 2016 to June 2016 and then from June 2018 to December 2023. During the period from July, 2016 to May, 2018 E-CLIA method was employed for testing of HIV, HCV and HBV using 4th generation HIV kits (Elecsys® HIV combi PT, Roche Diagnostics GmbH, Mannheim, Germany), HCV kits (Elecsys® Anti-HCV, Roche Diagnostics GmbH, Mannheim, Germany) and HBV kits (Elecsys® HBsAg II, Roche Diagnostics GmbH, Mannheim, Germany), on Cobas e411 platform. Rapid tests, if done, were performed by using HIV Tri-dot (Diagnostic Enterprises, India) for HIV, HCV Tri-dot (Diagnostic Enterprises, India) for HCV and Hepacard (Diagnostic Enterprises, India) for HBV.

Test for Syphilis was performed with either the Rapid Plasma Reagin card (RPR) method [CARBOGEN®, Tulip Diagnostics (P) Ltd., India] or Rapid Test Card (Aspen, Rapid Diagnostic Pvt. Ltd., India). The test for Malaria was done with rapid card test method as it is a rapid, visual and sensitive immunoassay for the qualitative diagnosis of all four Plasmodium Species, (Advantage Pan Malaria Card, J. Mitra & Co. Pvt. Ltd., India).

All the tests were performed as per the manufacturer's instructions and the standard operating procedures of the blood centre.

Statistical Analysis- The prevalence of individual TTIs was calculated for each year, and changes in trends were recorded for the seven years. In addition, sero-reactive donors were categorized concerning age, educational status and rural-urban background, to determine if any predictable relationship existed between sero-reactivity and these parameters.

RESULTS

A total of 46,304 healthy blood donors were screened for TTIs during the study period. Out of the 46,304 blood donors, 45,350 (97.9%) were males and 954 (2.06%) were females. All were voluntary, non-remunerated blood donors. The overall seroprevalence of TTIs was 2.05%; 2.05% in male donors and 1.78% in female donors (Table 1).

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Table 1: Sero-prevalence of TTIs in male & female blood donors

	Total Number	Number Sero-reactive	Seroprevalence (%)
Male Donors	45350	930	2.05
Female Donors	954	17	1.78
Total Donors	46304	947	2.05

The order of overall prevalence of TTIs in sero-reactive donors over seven years was HCV > HBV > Syphilis > HIV > Malaria (Table 2). Table 3 shows that out of the 947 sero-reactive donors, seven had a coinfection. Among these, HCV was the most prevalent, reported in six of these seven cases. In five of these, HIV infection was observed along with HCV. One of the donors had HCV along with syphilis and one had HBV along with syphilis.

Table 2: Indian studies showing prevalence of TTIs (ascending order) in blood donors.

Authors	Place	No. of Donors	Overall TTIs	HIV	HBV	HCV	VDRL	Malaria
Patel *et al.* [5]	Gujarat	20392	1.19	0.09	0.76	0.14	0.20	0.00
Bagde *et al.* [6]	Chhattisgarh	54831	1.45	0.31	0.75	0.065	0.22	0.1
NACO [11]	India	11645791	1.58	0.14	0.87	0.34	0.17	0.06
Thakur *et al.* [3]	Delhi	16925	2.038	0.201	1.111	0.431	0.29	0.006
Present Study	Punjab	46304	2.05	0.09	0.54	1.02	0.41	0.00
Chandekar *et al.* [4]	Maharashtra	76653	2.10	0.26	1.30	0.25	0.28	0.00
NACO [11]	Punjab	412478	2.64	0.14	0.65	1.35	0.49	0.01
Shrivastava *et al.* [7]	Madhya Pradesh	57942	2.7	0.20	1.8	0.42	0.31	0.008
Saini *et al.* [9]	Punjab	13035	2.81	0.26	1.02	1.53	-	-
Cherukat *et al.* [8]	Puducherry	28380	3.06	0.31	2.19	0.51	0.05	0.00
Bansal *et al.* [10]	Punjab	19689	3.50	0.18	0.42	1.67	1.23	0.00
Kumari *et al.* [11]	Punjab	42275	4.00	0.2	0.7	2.3	0.6	-
Rawat *et al.* [1]	Delhi	220482	4.36	0.32	1.61	0.73	1.62	0.06

Table 3: Co-infection among sero-positive blood donors.

Co-infection	Number of Donors	Prevalence in Sero-Reactive Donors (%)	Percentage of Co-infections
HCV + HIV	5	0.53	72
HCV + VDRL	1	0.105	14
HBV + VDRL	1	0.105	14
Total	7	0.74	100

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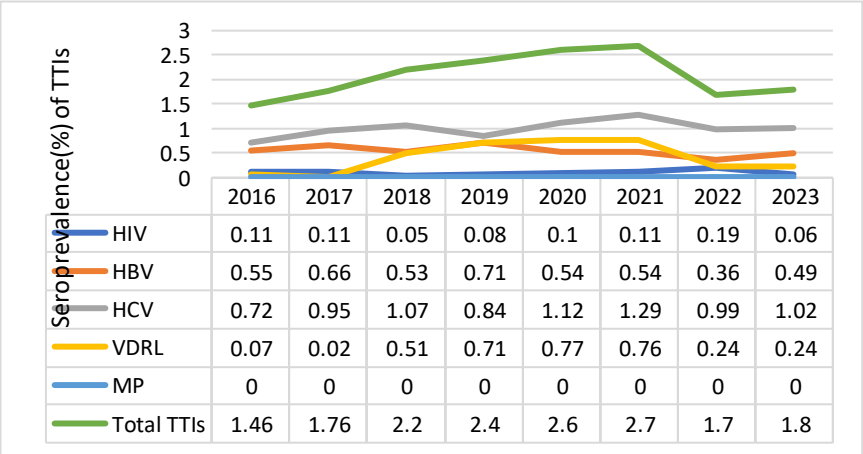
Fig. 1 shows the overall trend in seroprevalence and trends in seroprevalence of individual TTIs during the seven years. It was observed that the most common TTI over the seven years has been HCV. It's seroprevalence has shown a generally increasing trend and has increased during this period with the highest seroprevalence reported in 2021. The seroprevalence of HBV has remained more or less similar. The highest seroprevalence was observed in 2019 and the lowest in 2022. In the case of HIV, the highest seroprevalence was reported in 2022 and the lowest in 2018. The seroprevalence has varied over the seven years. However, no predictable increase or decrease in trend was observed during the study period. Like HCV, the prevalence of syphilis has shown a generally increasing trend and has increased from 2016 to 2023 with the highest seroprevalence reported in 2020. Malaria was never reported in our donors during the study period.



	2016	2017	2018	2019	2020	2021	2022	2023
HIV	0.11	0.11	0.05	0.08	0.1	0.11	0.19	0.06
HBV	0.55	0.66	0.53	0.71	0.54	0.54	0.36	0.49
HCV	0.72	0.95	1.07	0.84	1.12	1.29	0.99	1.02
VDRL	0.07	0.02	0.51	0.71	0.77	0.76	0.24	0.24
MP	0	0	0	0	0	0	0	0
Total TTIs	1.46	1.76	2.2	2.4	2.6	2.7	1.7	1.8

Fig. 1: Trends in prevalence of TTIs from 2016 to 2023

Fig. 2 shows the age-wise distribution of TTIs among the sero-reactive donors. It was observed that most of the sero-reactive donors belonged to the age group of 21-30 years followed by those in the age group of 31-40 years. Only 0.3% of the sero-reactive donors were reported in the age group of 61-65 years.

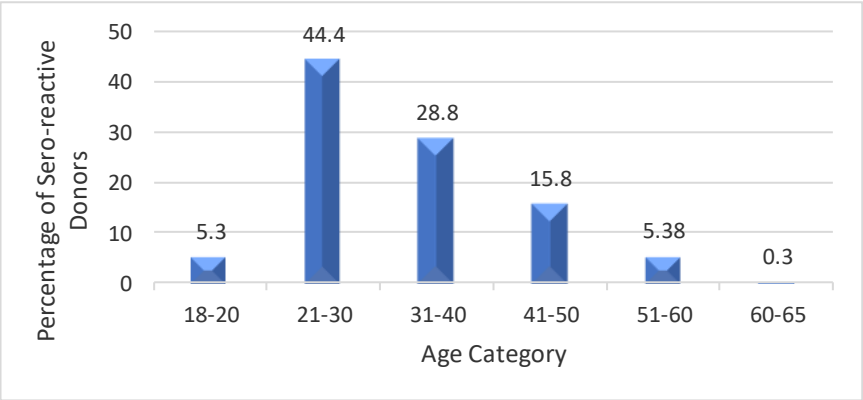


Fig. 2: Relationship of TTI sero-reactivity with donor age.

Data about the educational background of 281 was not available with us. Out of the remaining 666 donors, we observed that majority of the sero-reactive donors had obtained only up to secondary education or less or had no formal education. Further, 28.53% of the sero-reactive donors had education till senior secondary level only, while 19.37% among these were graduates and only 1.05% were post graduates (Fig. 3).

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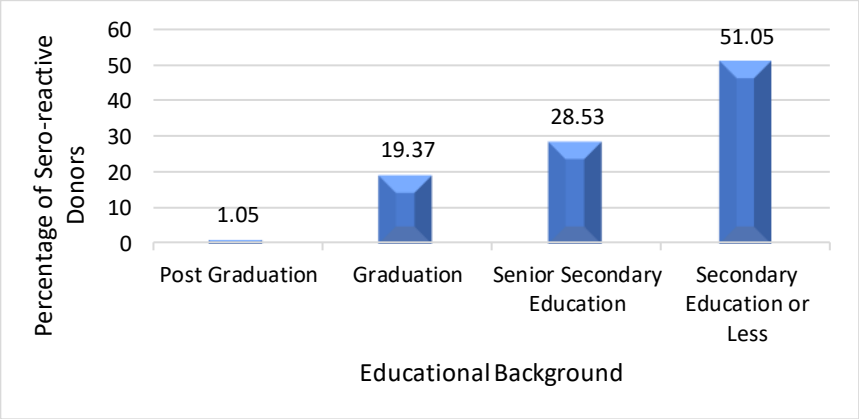

Fig. 3: Relationship of TTI sero-reactivity with educational background.

In terms of rural or urban residence, it was observed that the majority of the sero-reactive donors had a rural background as compared to an urban background (Fig. 4).

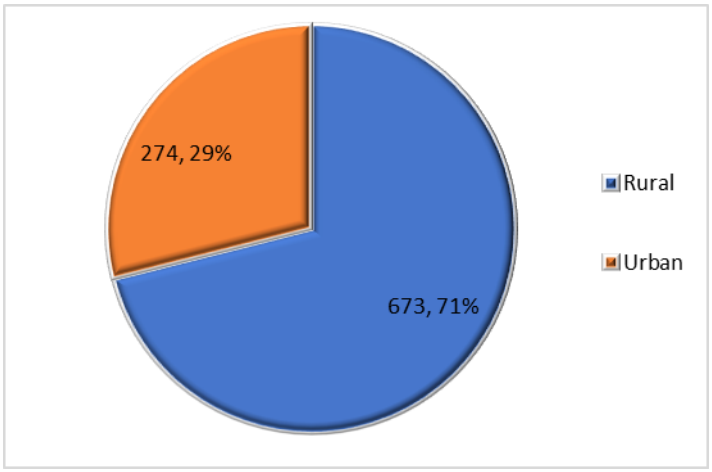

Fig. 4: Relationship of TTI sero-reactivity with rural/urban background.

DISCUSSION

In our study, we found that the overall seroprevalence of TTIs during the seven years was 2.05%. Like our findings, the seroprevalence of TTIs in blood donors reported by Thakur *et al.* and Chandekar *et al.* was 2.038% and 2.10% respectively [3,4]. In comparison to our findings, Patel *et al.* and Bagde *et al.* have reported lower seroprevalence rates of TTIs in their blood donors [5,6]. On the other hand, Shrivastava *et al.*, Cherukat *et al.* and Rawat *et al.* reported a higher TTI seroprevalence, in blood donors [1,7,8]. Even from Punjab, Saini *et al.*, Bansal *et al.*, and Kumari *et al.* have reported a higher seroprevalence of TTIs among blood donors, as compared to our findings [9-11]. A report published by National AIDS Control Organization (NACO), based on data from all the blood banks in India, observed that the overall seroprevalence of TTIs in 1,16,45,791 Indian blood donors was 1.58%, in the year 2015. In the same report, it was found that the overall seroprevalence of TTI's in blood donors of Punjab was 2.64% during the same period [12].

The order of overall prevalence of TTIs in sero-reactive donors over seven years was HCV > HBV > Syphilis > HIV > Malaria. The same order has also been observed in some of the other studies done in Punjab [11,12]. However, in a study carried out in Punjab by Bansal et al, it was observed that the seroprevalence of Syphilis was more than that of HBV, rest of the order remaining the same [10]. In comparison to our findings, the NACO report has observed that the order of seroprevalence in blood donors of India is HBV > HCV > Syphilis > HIV > Malaria [12]. Many other Indian studies have also observed that HBV is the most common TTI among their blood donors [3-8]. Our study shows that HCV is the most prevalent TTI among blood donors in Punjab. However, various other studies and especially the NACO report have found that

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HBV is the most prevalent TTI among blood donors in most parts of India.

It was observed that the most common TTI over the seven years has been HCV and its seroprevalence has shown a generally increasing trend during the study period. An increasing trend in HCV has also been reported by some other authors [1,5]. On the other hand, some of the studies observed a decrease in seroprevalence of HCV during their study period [7,13,14]. Makroo *et al.* and Saini *et al.* did not observe any change in the trend of seroprevalence of HCV during the respective study periods [2,9]. In the case of HBV and HCV, we observed variations in seroprevalence, over the seven years, however, no predictable increase or decrease in trend was observed. Many of the other studies have observed a decreasing trend in the seroprevalence of HIV and HBV in blood donors, over the years [1,5,7,13,14]. However, Saini *et al.* reported an increase in the same [9]. The prevalence of syphilis increased considerably during the years 2018 to 2021 and declined thereafter, but a noticeable increase was still observed during the seven years. A similar pattern was also reported by Patel et al in their study [5]. However, a decrease in the seroprevalence of syphilis has been reported by Rawat *et al.* and Shrivastava *et al.* [1,7]. During the study period, no case of malaria was reported. Malaria has been the least prevalent of the TTIs, with its seroprevalence ranging from 0.00 to 0.10 [1,3-11]. Overall, in our centre, TTI prevalence has increased over the last seven years. This seems to be related mainly to an increase in the prevalence of syphilis and HCV, over the same period.

Among the 947 sero-reactive donors, seven donors had a coinfection, with a prevalence rate of 0.74%. The overall prevalence of co-infections was 0.02%. HCV was the most common in case of co-infections. HCV along with HIV was the most prevalent coinfection (0.53%), followed by HCV along with syphilis and HBV along with syphilis with a prevalence rate of 0.105% each. Chandekar *et al.* reported 0.007% as the overall seropositivity of donors with multiple infections, which is much lower than our findings. Unlike our findings, it was reported in their study, that HIV was the most common in case of multiple infections [4]. In another study, HBV was found to be the most prevalent in co-infections [8].

These differences in the prevalence of different TTIs, and trends over some time, as shown in studies from different parts of India, may be attributable to regional variations, differences in types of donors, individual donor characteristics, pre-donation donor screening protocols and post-donation testing methods employed. [1,2,6-8]

As reported in other Indian studies also, most blood donors in the present study were males (97.9%) as compared to females (2.06%) [6,8,9,13]. Also, the overall seroprevalence of TTIs was higher in male donors (2.05%) as compared to female donors (1.78%) which is like findings that have been reported in other studies [9,13]. However, since the sample size of female donors is significantly lower as compared to male donors, this difference in seroprevalence may not be an accurate representation.

Concerning age-wise distribution, it was observed that most of the sero-reactive donors (44.4%) belonged to the age group of 21-30 years followed by those in the age group of 31-40 years (28.8%). Only 0.3% of the sero-reactive donors were reported in the age group of 61-65 years. Similar findings have been reported in some other Indian studies too and may be attributable to higher sexual activity and preponderance towards high-risk behaviour in younger individuals. [5,7,13]

In our study, most of the sero-reactive donors (51.05%) had obtained only up to secondary education or less or had no formal education. Further, 28.53% of the sero-reactive donors had education till senior secondary level only, while 19.37% among these were graduates and only 1.05% were postgraduates. A similar finding has been reported by Cheema et al, who found that TTI seropositivity was low in postgraduate and graduate donors as compared to donors with matric or intermediate education [15]. On the contrary Cherukat *et al.* found the highest rate of TTI's among those who were pursuing a bachelor's degree. However, they concluded that the finding was due to skewing as most of their donors belonged to the same category [8]. The inversely proportional relation of level of education and seroprevalence of TTI's may be due to more awareness, and knowledge about safe practices and low-risk behaviour among more educated individuals. [16]

It was observed that 71% of the sero-reactive donors had a rural background while only 29% resided in urban areas. Contrary to our findings, Shrivastava et al, reported that 70% of the sero-reactive donors belonged to urban areas and only 30% of the donors resided in

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rural areas. [7] The higher seroprevalence of TTIs in donors with a rural background may be attributed to a lack of education, awareness, and safe practices. [17]

CONCLUSIONS

Blood Transfusion Services are an important part of the healthcare system. Blood/blood components must be as safe as possible for the transfusion recipients. This can be achieved by adopting a multi-pronged strategy aimed at recruiting and retaining voluntary non-renumerated blood donors, promoting awareness and education about the importance of safe practices and low-risk behaviour, especially among the younger population belonging to different social/educational backgrounds.

In addition, the adoption of more stringent pre- and post-donation screening protocols, including the adoption of more sensitive testing methodologies, like Nucleic Acid Amplification testing, would go a long way in ensuring the safest possible blood supply.

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