

Original Research

“Trends in sero-prevalence of various transfusion transmissible infections among replacement and voluntary blood donors at a regional blood transfusion centre in north India: A 10 year study”

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ABSTRACT:

Background and Aim: It is estimated that each blood unit transfusion carries 1% chance of complications including transfusion transmitted infections (TTIs) to blood recipients. The developed nations have greatly reduced the risk of TTIs with effective blood donor selection and newer testing methodologies. But TTIs still pose a significant risk to safe blood transfusion in developing countries including India. Continuous monitoring of trends of TTIs among blood donors is essential for the assessment of the accurate estimate of risk of TTIs and to create strategies to improve safety of blood transfusion. The aim of the current study was to assess the trends in seroprevalence of various TTIs among voluntary and replacement blood donors over a 10 year period at a Regional Blood Transfusion Centre in North India.

Materials & Methods: A retrospective review of blood donor records was carried for a 10 year period extending from January 2010 to December 2019. The study was conducted in the Postgraduate Department of Transfusion Medicine, Government Medical College Jammu. Screening for HIV, HBV and HCV were done by using 3rd generation ELISA technique. RPR-Rapid Plasma Reagin Kit and Rapid Immunochromatographic tests were used for screening of syphilis and malaria, respectively.

Results: A total of 320914 apparently healthy blood donors donated blood and were screened for TTIs during the study period. Among them 277169 (86.4%) were replacement donors and 43745(13.6%) were voluntary donors. 308399(96.1%) were male donors and 12515(3.9%) were female donors. The overall prevalence of TTIs among all donors was found to be 1.30% with prevalence of HIV, HBV, HCV, syphilis and malaria being 0.07%, 0.50%, 0.15%, 0.56% and 0.001% respectively. The overall seroprevalence of all TTIs among replacement donors (1.35%) was higher as compared to voluntary donors (0.95%). Seroprevalence of HIV, HBV showed a decreasing trend while there was an increasing trend in HCV infection.

Conclusion: Our study concluded that TTIs still pose a considerable risk to safe blood transfusion services and this risk is more with replacement blood donors as compared to voluntary blood donors. Meticulous testing of donated blood with newer techniques and promotion of voluntary blood donation is needed to enhance safety of blood transfusions in the country.

Keywords: Transfusion transmitted infections, replacement blood donors, voluntary blood donors, human immunodeficiency virus, hepatitis B virus, hepatitis C virus, syphilis, malaria

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BACKGROUND AND AIM

Safe blood transfusion services (BTS) is a vital component of any healthcare delivery system, with millions of blood transfusions being carried out to save lives of the patients around the globe each year.

(1). But it is well established that no transfusion is risk-free and it is estimated that each blood unit transfusion carries 1% chance of complications including transfusion transmitted infections (TTIs) which may result in morbidity and mortality in blood

recipients. (2) Recent rapid advancements in medical and surgical fields have led to a rise in the demand of blood and its components for transfusion. In India, National AIDS Control Organization (NACO) reported an annual blood collection of 11.1 million units in 2017 against a recently estimated need of 26.4 million units. (3) This has become a challenging task to meet such raised needs with simultaneously ensuring safe supply of blood products especially for developing nations like India where the prevalence rate of transfusion transmitted infections is high as compared to that of developed nations. (4)

In India, all blood donations are needed to be tested for human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), syphilis and malaria before issuing blood for transfusion in order to ensure safety of BTS, as mandated by Drugs and Cosmetics Act, 1945. (5) The extent of various TTIs varies not only among and within the countries but also among the type of blood donors whether voluntary or replacement blood donors depending upon the prevalence of TTIs in the particular population. The developed nations have greatly reduced the risk of TTIs with effective blood donor selection and newer testing methodologies including nucleic acid testing (NAT). (6) But TTIs still pose a significant risk to safe blood transfusion in developing countries including India, for want of organized blood transfusion services and newer testing modalities. Thus a continuous monitoring of trends of TTIs among blood donors is not only essential for the assessment of the accurate estimate of risk of TTIs but also helps in the creation of long-term strategies to improve safety of blood transfusion and spread of TTIs in local population. (7-8)

The aim of the current study was to assess the trends in seroprevalence of various TTIs among voluntary and replacement blood donors over a 10 year period at a regional blood transfusion centre in north India.

MATERIALS & METHODS

STUDY AREA & DESIGN

The data was collected from the blood donor records in the Department of Immunohaematology and Blood Transfusion Medicine, Government Medical College, Jammu, Jammu & Kashmir, India. The Department operates two blood banks and one blood storage centre. The facility collects blood from both replacement and voluntary blood donors. All the donated blood is tested for HIV-1&2, HBV, HCV, syphilis and malaria in strict compliance with national policies and guidelines.

A retrospective descriptive study of blood donors' data who donated blood in the blood banks of the Department was conducted from January 2010 to December 2019. The data about blood donor age, gender, type of donation-replacement or voluntary and TTI testing outcome was done.

STUDY POPULATION

Both voluntary and replacement blood donors were included in the study. Blood was collected from apparently healthy blood donors who satisfied blood donor eligibility criteria for age (18-65 years), weight (> 45Kg), hemoglobin ($\geq 12.5\text{gm}\%$), pulse rate (60-100bpm, regular), systolic blood pressure (100-160 mmHg), diastolic blood pressure (60-100mmHg), normal body temperature, etc.

Blood donors were subjected to detailed medical history questionnaire and general physical examination before being selected for blood donation to rule out any past or present medical illness as per national guidelines. Written consent was also taken from each donor before blood donation.

TTI TESTING METHODS

A 5ml sample was obtained into EDTA vial for TTI testing from the blood donor units at the time of bleeding and blood was screened for hepatitis B surface antigen (HBsAg), anti-hepatitis C virus (HCV) antibodies and human immunodeficiency virus-1 & 2 (HIV-1 & 2) antibodies using third generation enzyme-linked immunosorbent assay (ELISA) test kits. Syphilis was tested by RPR-Rapid Plasma Reagin kit and malaria was tested by antigen based rapid immune-chromatographic test. All tests were done as per manufacturer's instructions. Quality of the reagent was tested beforehand. Appropriate control was incorporated in all test procedures. All reactive samples were labeled as sero-positive, disinfected and discarded.

STATISTICAL ANALYSIS

The collected data was entered in Microsoft Office Excel worksheet and percentage and proportions for each TTI was calculated. Prevalence of TTI was expressed as the number of sero-positive samples per year. Prevalence of HIV, HBV, HCV, syphilis and malaria were expressed in percentages per year with respect to donor type-voluntary and replacement.

ETHICS APPROVAL

The permission to conduct the study was taken from Head of the Department and clearance was obtained from Institutional Ethics Committee (IEC No:652).

RESULTS

BASIC CHARACTERISTICS OF BLOOD DONORS

A total of 320,914 blood donations were made by apparently healthy blood donors during the 10 year study period from 2010 to 2019. There was an increase (11.6%) in number of blood donations over time with 27,696 donations in 2010 to 30911 donations in 2019.

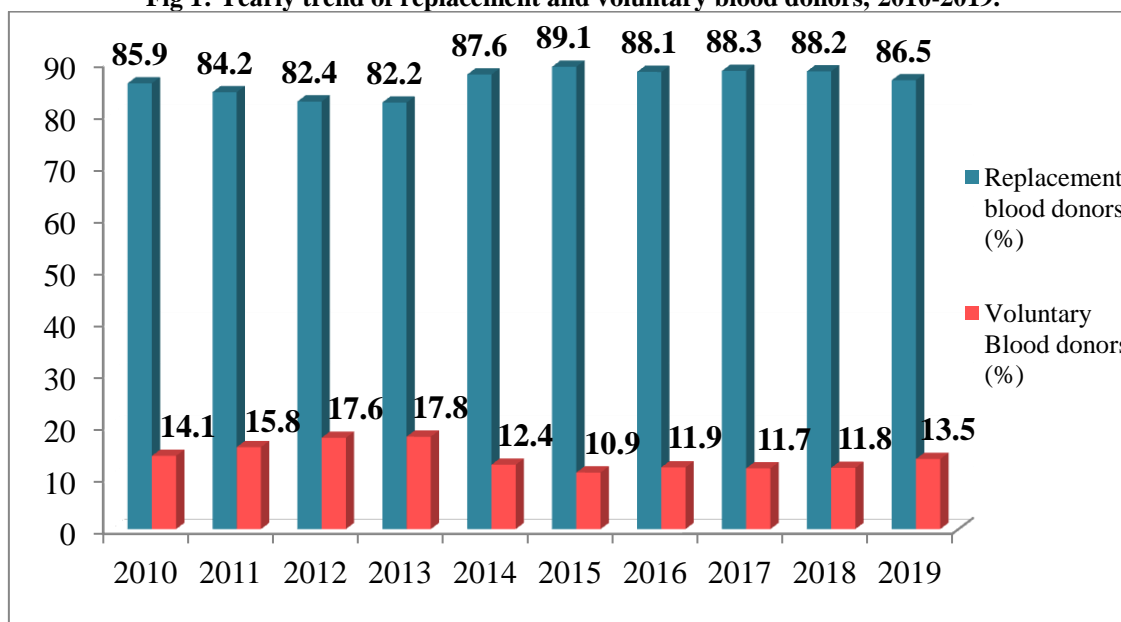
Of all the blood donors 308,399 (96.1%) were male and 12515 (3.9%) were female. The majority of blood donors were replacement blood donors (86.4%) and the remaining were voluntary blood donors (13.6%).

Yearly distribution and trend of replacement and voluntary blood donors is shown in Table 1 & Fig 1.

Table 1: Yearly distribution of replacement and voluntary blood donors, 2010-2019

Year	Total Blood Donations N	Replacement Blood Donors N (%)	Voluntary Blood donors N (%)
2010	27,696	23,788 (85.9%)	3,908 (14.1%)
2011	30,683	25,846 (84.2%)	4,837 (15.8%)
2012	30,029	24,751 (82.4%)	5,278 (17.6%)
2013	31,209	25,650 (82.2%)	5,559 (17.8%)
2014	38,265	33,523 (87.6%)	4,742 (12.4%)
2015	35,998	32,057 (89.1%)	3,941 (10.9%)
2016	31,975	28,171 (88.1%)	3,804 (11.9%)
2017	30,668	27,091 (88.3%)	3,577 (11.7%)
2018	33,480	29,544 (88.2%)	3,936 (11.8%)
2019	30,911	26,748 (86.5%)	4,163 (13.5%)
Total (2010-2019)	320,914	277,169 (86.4%)	43,745 (13.6%)

Fig 1: Yearly trend of replacement and voluntary blood donors, 2010-2019.



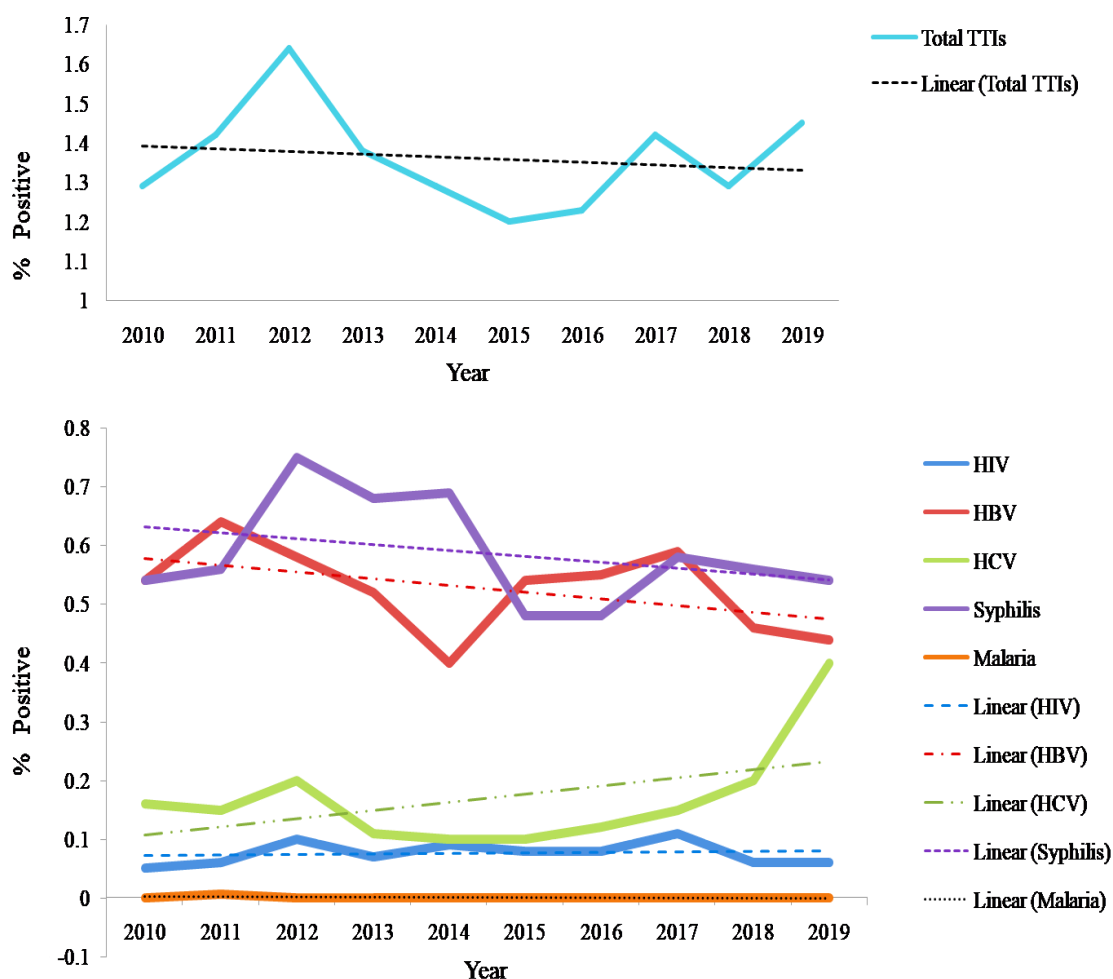
PREVALENCE AND TRENDS OF TTIS IN BLOOD DONORS

In the present study, the overall prevalence of TTIs among all blood donors was found to be 1.30% with prevalence of HIV, HBV, HCV, syphilis and malaria being 0.07%, 0.50%, 0.15%, 0.56% and 0.001% respectively. Table 2 & Fig 2 show the prevalence and trends of positive TTIs among all blood donors.

Table 2: Yearly sero-prevalence of various TTIs in all blood donors, 2010-2019.

Year	Donations (R+V) N	HIV		HBV		HCV		Syphilis		Malaria		Total TTIs	
		N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
2010	27696	14	(0.05)	141	(0.51)	42	(0.15)	143	(0.52)	0	(0)	340	(1.23)
2011	30683	16	(0.05)	194	(0.63)	46	(0.15)	165	(0.54)	2	(0.006)	423	(1.38)
2012	30029	29	(0.09)	160	(0.53)	59	(0.19)	215	(0.71)	0	(0)	463	(1.54)
2013	31209	20	(0.06)	153	(0.49)	31	(0.10)	202	(0.65)	0	(0)	406	(1.30)
2014	38265	37	(0.09)	158	(0.41)	40	(0.10)	267	(0.70)	0	(0)	502	(1.31)
2015	35998	27	(0.07)	190	(0.53)	33	(0.09)	168	(0.47)	0	(0)	418	(1.16)
2016	31975	27	(0.08)	169	(0.53)	37	(0.11)	154	(0.48)	0	(0)	387	(1.21)
2017	30668	31	(0.10)	169	(0.55)	42	(0.14)	164	(0.53)	0	(0)	406	(1.32)
2018	33480	20	(0.06)	150	(0.45)	65	(0.19)	184	(0.55)	0	(0)	419	(1.25)
2019	30911	18	(0.06)	130	(0.42)	108	(0.35)	154	(0.50)	0	(0)	410	(1.33)
Total	320914	239	(0.07)	1614	(0.50)	503	(0.15)	1816	(0.56)	2	(0.001)	4174	(1.30)

Fig 2: Trends in sero-prevalence of total transfusion-transmissible infections (TTIs) and Human-immunodeficiency virus (HIV), Hepatitis B virus (HBV), Hepatitis C virus (HCV), Syphilis and Malaria among all (R+V) blood donors in Department of Blood Transfusion Medicine Government Medical College Jammu, 2010-2019.

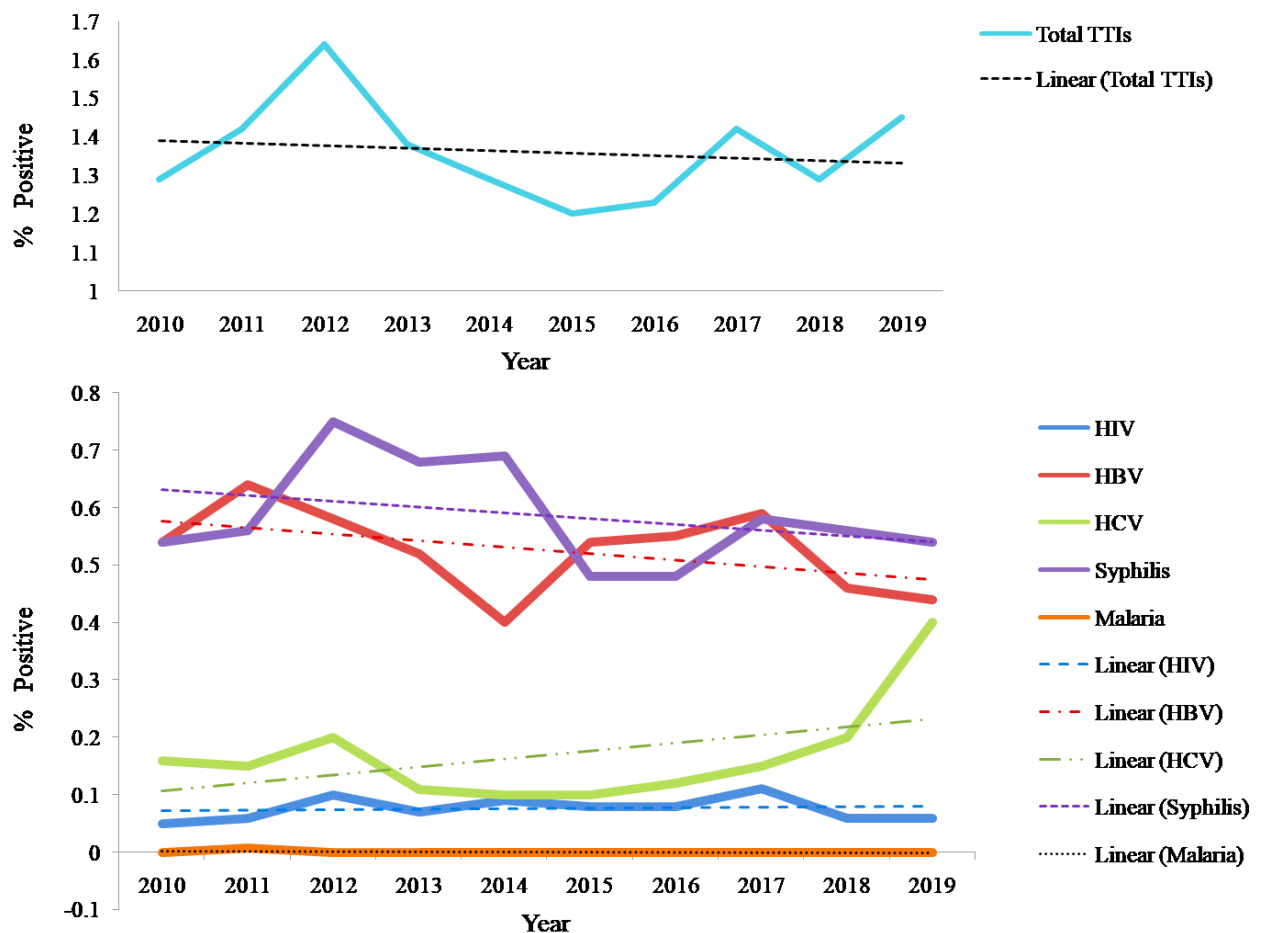


The overall prevalence of all TTIs among replacement blood donors was found to be 1.35% with prevalence of HIV, HBV, HCV, syphilis and malaria being 0.08%, 0.52%, 0.16%, 0.58%, and 0.001% respectively. Table 3 & Fig 3 show the prevalence and trends of positive TTIs among replacement blood donors.

Table 3: Yearly sero-prevalence of various TTIs in replacement (R) blood donors, 2010-2019.

Year	Donations (R) N	HIV		HBV		HCV		Syphilis		Malaria		Total TTIs	
		N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
2010	23788	13	(0.05)	129	(0.54)	37	(0.16)	128	(0.54)	0	(0)	307	(1.29)
2011	25846	15	(0.06)	166	(0.64)	39	(0.15)	144	(0.56)	2	(0.007)	366	(1.42)
2012	24751	26	(0.10)	145	(0.58)	49	(0.20)	187	(0.75)	0	(0)	407	(1.64)
2013	25650	17	(0.07)	134	(0.52)	28	(0.11)	175	(0.68)	0	(0)	354	(1.38)
2014	33523	32	(0.09)	135	(0.40)	34	(0.10)	233	(0.69)	0	(0)	434	(1.29)
2015	32057	26	(0.08)	174	(0.54)	32	(0.10)	153	(0.48)	0	(0)	385	(1.20)
2016	28171	24	(0.08)	154	(0.55)	33	(0.12)	137	(0.48)	0	(0)	348	(1.23)
2017	27091	29	(0.11)	159	(0.59)	41	(0.15)	157	(0.58)	0	(0)	386	(1.42)
2018	29544	18	(0.06)	137	(0.46)	60	(0.20)	167	(0.56)	0	(0)	382	(1.29)
2019	26748	16	(0.06)	119	(0.44)	107	(0.40)	146	(0.54)	0	(0)	388	(1.45)
Total	277169	216	(0.08)	1452	(0.52)	460	(0.16)	1627	(0.58)	2	(0.001)	3757	(1.35)

Fig 3: Trends in sero-prevalence of total transfusion-transmissible infections (TTIs) and Human-immunodeficiency virus (HIV), Hepatitis B virus (HBV), Hepatitis C virus (HCV), Syphilis and Malaria among replacement(R) blood donors in Department of Blood Transfusion Medicine Government Medical College Jammu, 2010-2019.

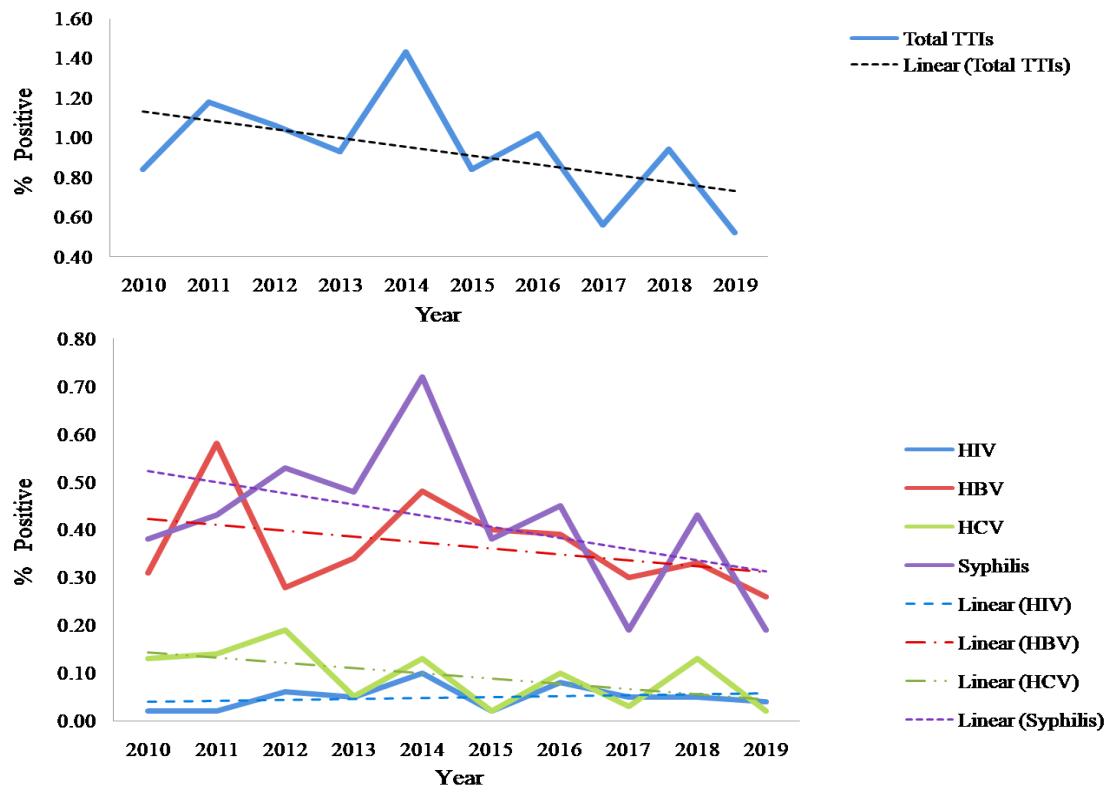


The overall prevalence of all TTIs voluntary blood donors was found to be 0.95% with prevalence of HIV, HBV, HCV, syphilis and malaria being 0.05%, 0.37%, 0.09%, 0.43%, and 0% respectively. Table 4 & Fig 4 show the prevalence and trends of positive TTIs among voluntary blood donors.

Table 4: Yearly sero-prevalence of various TTIs among voluntary (V) blood donors, 2010-2019.

Year	Donations (V) N	HIV		HBV		HCV		Syphilis		Malaria		Total TTIs	
		N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
2010	3908	1	(0.02)	12	(0.31)	5	(0.13)	15	(0.38)	0	(0)	33	(0.84)
2011	4837	1	(0.02)	28	(0.58)	7	(0.14)	21	(0.43)	0	(0)	57	(1.18)
2012	5278	3	(0.06)	15	(0.28)	10	(0.19)	28	(0.53)	0	(0)	56	(1.06)
2013	5559	3	(0.05)	19	(0.34)	3	(0.05)	27	(0.48)	0	(0)	52	(0.93)
2014	4742	5	(0.10)	23	(0.48)	6	(0.13)	34	(0.72)	0	(0)	68	(1.43)
2015	3941	1	(0.02)	16	(0.40)	1	(0.02)	15	(0.38)	0	(0)	33	(0.84)
2016	3804	3	(0.08)	15	(0.39)	4	(0.10)	17	(0.45)	0	(0)	39	(1.02)
2017	3577	2	(0.05)	10	(0.30)	1	(0.03)	7	(0.19)	0	(0)	20	(0.56)
2018	3936	2	(0.05)	13	(0.33)	5	(0.13)	17	(0.43)	0	(0)	37	(0.94)
2019	4163	2	(0.04)	11	(0.26)	1	(0.02)	8	(0.19)	0	(0)	22	(0.52)
Total	43745	23	(0.05)	162	(0.37)	43	(0.09)	189	(0.43)	0	(0)	417	(0.95)

Fig 4: Trends in sero-prevalence of total transfusion-transmissible infections (TTIs) and Human-immunodeficiency virus (HIV), Hepatitis B virus (HBV), Hepatitis C virus (HCV), Syphilis and Malaria among voluntary blood donors in Department of Blood Transfusion Medicine Government Medical College Jammu, 2010-2019.



DISCUSSION

Blood transfusion has now become an essential and life saving procedure in treatment of many patients but it also carries the risk of transfusion of life threatening transfusion transmissible infections. (9) In the developed world the transmission rates of HIV, HBV, HCV and syphilis through blood transfusion have been reported to be around 1 in 2-5 million, 1 in 0.5-1million, 1 in 2-4 million, 6 in a million, respectively.(10,11) The remarkably low risk of TTIs in developed countries is owing to their safeguard measures which include exclusive collection of blood from voluntary non-remunerated blood donors, risk-based blood donor selection, and the use of high-performance laboratory testing often consisting of parallel serological testing and nucleic acid testing (NAT), in addition to robust quality assurance systems. (12,13)

But the risk of TTI transmission seems still higher in developing countries. The national policy for blood transfusion services in our country is of recent origin and the transfusion services are hospital based and fragmented. WHO recommends collection of blood from voluntary regular non-remunerated donors who are found to have a lower risk of TTIs in comparison to family replacement and commercial blood donors. (14,15)

Accurate estimates of risk of TTIs are essential for monitoring the safety of blood supply and evaluating the efficacy of the screening procedures employed for TTI testing. (16) Moreover, in a well organized healthcare system with quality blood transfusion services, the prevalence of TTIs among blood donors can serve as a reliable tool in estimating these infectious agents in general population that can act as a foundation for public healthcare policy formulation. (17)

The majority of blood donors in our study were males (96.1%) as reported in other studies done by different authors with more than 95% blood donors being males.(18,19,20,21) This is due to less females turning up for blood donation and majority of them being deferred due to high prevalence of anemia ($Hb < 12.5 gm\%$).

In the present study out of total blood donors, replacement donors were 86.4% while voluntary blood donors were 13.6%. Similar predominance of replacement blood donors (64.78-99.48%) was observed in some studies. (18,20,22,23) In contrast, voluntary blood donors constituted majority of donors (>90%) in other studies. (19,21) It shows replacement blood donation is still highly prevalent in most parts of our country. This seems due to lack of awareness

about blood donation and misconception about blood donation procedures.

The seroprevalence of various TTIs observed in various studies from different regions of India is compared and shown in Table 5. The overall seroprevalence of TTIs in our study was found to be 1.30% which was less as compared to TTI seroprevalence (1.91-3.9%) observed in most of the studies from different parts of the country.(18,20,22,24,25,26) TTI seroprevalence (1.17-1.29%) in some studies was found to be comparable to that of our study. (19,21) This might be as a result of differences in seroprevalence of various TTIs in general population of different regions of the country and as well as due to use of different methods for testing and use of different generation of ELISA test kits having different sensitivities and specificities. In our study the seroprevalence of TTIs was found to be lesser in voluntary blood donors as compared to replacement blood donors. Similar results were observed in various other studies. (18,20,22,27) The higher seroprevalence of TTIs among replacement blood donors might be due to number of factors including concealing of high risk behaviour and paid donors posing as relatives. Emphasis should be to maximize voluntary blood donations through public awareness campaigns and encouraging voluntary blood donation camps so as to minimize the risk of TTIs.

The trend of overall seroprevalence of TTIs in our study showed a slight decline. The decline in seroprevalence of TTIs was more in voluntary blood donors as compared to replacement blood donors, there by again emphasizing the need for voluntary blood donation to reduce the risk of TTIs. Similar declining trends were observed in other studies. (18,22,28) Among individual TTIs the HIV seropositivity in our study was 0.07% which was lesser as compared to HIV prevalence of 0.22% (0.17-0.29%) in India as reported by NACO.(29) Several other studies have also shown a gradual decline in HIV seroprevalence over the years. (18,21,22,25) There is a continuous decline in HIV seropositivity in recent years as observed in our study. This is due to successive implementation of National AIDS Control

Programme by NACO which is aimed at increasing awareness about HIV infection among general public and providing diagnosis and treatment services to HIV infected persons.

HBV seropositivity of 0.50% in our study was also found to be less as compared to WHO reported prevalence of 2-7% in Indian population and similar studies in blood donors. (30) In many studies including present study HBV seropositivity was found to decline among blood donors over the years. (18,21,22) This is due to effective implementation of national hepatitis B immunization programme in the country and increasing awareness of the disease in the population. This could also be due to the fact that blood donors are selected only after their thorough medical history and physical examination.

HCV seropositivity of 0.15% in our study was comparable to some studies. (20,21) It was found to be lesser as compared to other studies. (18,22,24) HCV seroprevalence showed a rising trend in our study as in some other studies.(18,27,31) This might be due to non-availability of vaccination, lack of awareness about its routes of transmission and changing risk behaviour patterns among general population.

Syphilis (0.56%) was found to be the most common TTI in our study. Other studies have shown seropositivity ranging from 0.001% to 0.9%. (18,19,21,22,24,25,26) Wide variation in syphilis seropositivity might be due to different testing kits and differences in awareness and high risk behavioural patterns in regional populations.

Malaria showed a seropositivity of 0.001% in our study which was comparable to that of other studies. (19,21,22,) The seroprevalence of malaria is dependent upon the malarial endemicity of the area.

CONCLUSION

Our study concluded that TTIs still pose a considerable risk to safe blood transfusion services and this risk is more with replacement blood donors as compared to voluntary blood donors. Meticulous testing of donated blood with newer techniques and promotion of voluntary blood donation is needed to enhance safety of blood transfusions in the country.

Table 5: Comparison of seroprevalence of various TTIs as observed in various studies from different regions of India.

Place	Study	Seroprevalence of TTIs (%)						
		HIV	HBV	HCV	Syphilis	Malaria	Overall TTIs	
North India	Jammu	Present study	0.07	0.50	0.15	0.56	0.001	1.30
	Delhi	Makroo RN et al ¹⁸	0.24	1.18	0.43	0.23	-	2.09
	Haryana	Arora D et al ²⁴	0.3	1.7	1.0	0.9	-	3.9
	Lucknow	Chandra T et al ²²	0.15	1.59	0.47	0.014	0.009	2.23
South India	Andhra Pradesh	Divyashree BN et al ¹⁹	0.14	0.82	0.02	0.13	0.03	1.17
	Karnataka	Pallavi P et al ²⁰	0.44	1.27	0.23	0.28	0	2.22
West India	Maharashtra	Patil PU et al ²¹	0.131	1.027	0.1409	0.001	0.01	1.29
	Maharashtra	Bharti KS et al ²⁵	0.46	1.27	0.06	0.12	0	1.91
East India	West Bengal	Bhattacharya P et al ²⁶	0.28	1.46	0.31	0.73	-	2.8

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