Original Article

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Transfusion Medicine Section

Prevalence and Trends of Transfusion Transmissible Infections in Blood Donors in a Tertiary Care Centre- An Institutional 4-year Retrospective Study

SHWETA WASUDEO DHOTE[1], ABHINITI RAHUL SRIVASTAVA[2], IQBAL SINGH[3]

ABSTRACT

Introduction: In today's time, safe transfusion begins with the screening and confirmation of availability of healthy donors. An important criterion to make safe blood available for one and for all is to try and prevent Transfusion Transmitted Infections (TTIs); and once if a donor is identified to be reactive for any one of the TTIs, then to notify and counsel them.

Aim: To study the seroprevalence and trends of TTIs in blood donors at MGM Medical College and Hospital, Navi Mumbai, Maharashtra, India.

Materials and Methods: This retrospective study was done in the Department of Immunohaematology and Blood Transfusion (IHBT) at MGM Medical College and Hospital, Navi Mumbai, Maharashtra, India for period of four years from January 2017 to December 2020 (48 months). Screening for anti-Human Immunodeficiency Virus (HIV)-1/2, anti-Hepatitis C Virus (HCV), and Hepatitis B surface Antigen (HBsAg), Venereal Disease Research Laboratory (VDRL) for syphilis, and slide test for malaria were done. Data was collected from various registers within the blood centre. It was entered in MS Excel spreadsheets and calculation was done for calculating the prevalence. R-square value was used to determine the trend of TTIs.

Results: A total of 19,864 donors were analysed for prevalence of TTIs from 2017 to 2020. Of these 99.16% were voluntary donors and 0.84% were replacement donors. Prevalence of TTI in total donors was 1.11%. Prevalence of hepatitis B was highest (0.84%) followed by syphilis (0.11%), HIV (0.07%) and HCV (0.09%) and malaria (0%). Prevalence was more in male replacement donors.

Conclusion: The prevalence of TTI in total donors was 1.11%. The number of total blood donations has been on the rise. Cases of HCV were steadily declining, but HIV, HBsAg, and syphilis showed a non linear trend. Strict adherence to the donor selection rules is needed to supply quality and safe blood to the patient.

Keywords: Enzyme linked immunosorbent assay, Safe blood, Screening, Seroconversion, Voluntary donation

INTRODUCTION

Blood products save millions of patients globally. The recipients are also at risk of various complications of transfusion for e.g., TTIs. To provide safe blood, adherence to the guidelines of the national program for donor selection and recruitment, is recommended [1]. In India, the National AIDS Control Organisation (NACO) and National Blood Transfusion Council (NBTC) are the prime bodies responsible for the functioning of blood transfusion services and blood safety. Guidelines provided by them are used for donor selection [2].

A standard questionnaire, haemoglobin concentration and medical examination are carried out to select donors [3]. The donor is bled, and samples are obtained to test for the presence of TTIs. Non reactive units are used for transfusion. Reactive units are discarded according to the biowaste management guidelines of the centre [4]. Through blood and blood product's transfusion, bacteria, viruses, prions, and parasites can be transmitted [5]. In many countries, screening of infections such as chagas disease, Human T Cell Lymphotropic Viruses I/II (HTLV) are also recommended. In few countries TTIs have been reduced over the last 20 years [5]. The reporting of these infections by the blood transfusion centres gives the medical researchers an idea about the magnitude of TTIs in otherwise healthy populations [6]. Complete prevention of TTIs is not guaranteed because commonly used laboratory tests are not able to detect the window period infections. The presence of immunologically variant viruses, non seroconverting silent carriers, laboratory testing errors and poor-quality control of laboratory tests make the scenario difficult for ensuring provision of safe blood [7]. The mandatory screening of the following infections in India i.e., HIV, HBsAg, HCV, syphilis and Malaria by using one test each of high sensitivity helps in provision of safe blood to the patients [5,8].

Most centres are using Enzyme Linked Immunosorbent Assay (ELISA) but Nucleic Acid Testing (NAT) is being increasingly used for the same in many blood centres to further improve blood safety. It is not mandated by national authorities yet [9]. WHO implemented a detailed strategy for the transfusion protocol that ensured well planned transfusion services, adequate promotion of voluntary donation, efficacious removal of TTIs seropositive samples from the inventory, and foundation of a definite quality control system [10]. Majority of the blood centres in India use ELISA for the serologic screening for TTIs. NAT is also known to offer good accuracy, consistency, reliability, and high throughput. Although they appear to be effective replacements for ELISA, the scarcity of detailed published research in support of the same in a pandemic stricken country, make it difficult to make it compulsory as a guideline [11].

With the implementation of strict donor criteria and use of sensitive screening tests, it may be possible to reduce the incidence of TTI in the Indian scenario [12]. The present study was aimed at collecting the donor's general profile, emphasising the seroprevalence of TTIs amongst donors. Some knowledge was gained about the various blood safety measurements. A rough estimate of the infection rate and trends of the TTIs were studied. Evaluation of the potential risk groups in an appropriate way, stringent donor selection and use of better screening methods could help in provision of safe blood.

The study was conducted keeping the following objectives:

- To know the prevalence of TTIs among the voluntary and replacement blood donors.

- To study the age wise distribution of reactive TTIs in the blood donors.
- To see the relationship of blood donors with TTIs according to the gender.
- To calculate HBsAg, HCV, HIV, malaria, and syphilis prevalence among donors.

MATERIALS AND METHODS

This retrospective study was conducted at Department of IHBT of a tertiary care hospital, located in Kamothe, Navi Mumbai, Maharashtra, India, for a period of four years i.e., from January 2017 to December 2020. Data was collected from the records in the blood bank for a period of four years and the master register was used to confirm the data. Data was analysed over one month in March 2021. Approval was obtained by the Institutional Ethical Committee (Approval Number N- EC/2021/02/28).

Inclusion criteria: All the donated blood units, voluntary and replacement, were screened for TTIs in the Department of IHBT during a period of four years from January 2017 to December 2020 were included in the study.

Exclusion criteria: Donors tested for apheresis procedures were excluded from the study.

Over the four years, different kits were used for the TTI screening of all donated blood to screen for HIV, HBsAg, HCV, syphilis, and malaria. Pilot tubes were used for the testing.

Following commercially available kits or reagents were used:

1. HIV- J.Mitra, Meril (4th generation)
2. HbsAg- Span, Meril, J. Mitra (3rd generation)
3. HCV- Meril, J. Mitra (3rd generation)
4. VDRL- Biolab, Tulip (RPR)
5. Malaria- Field stain A, Field stain A

ELISA enzyme: ELISA was done using automated ELISA Washer (LIS WASH 3000-Tulip) and reader (Mode PR 4100 Microplate reader-BIORAD). The RPR (Rapid Plasma Reagin) method was used to syphilis. Slides for malaria parasite were stained with Field Stain A and B and screened under the microscope. Controls, procedures, and cut-off values for reactive and non reactive samples were calculated as per commercially available kits' instruction manuals.

STATISTICAL ANALYSIS

Microsoft excel and Microsoft word were used to compile the article. Basic descriptive statistics and graphs were prepared using Statistical Package for the Social Sciences (SPSS). The R square is calculated by curve fitting method. R square value was applied to determine the trend of HBsAg, HCV, HIV, malaria, and syphilis over the study period.

RESULTS

Total 19,864 units were collected during the study period out of which 99.17% (19698) were voluntary and 0.83% (166) was replacement donors [Table/Fig-1]. Out of the total donors, 92.66% (18407) were male and 7.34% (1457) were female donors [Table/Fig-2]. A 216 voluntary donors were positive for TTIs in comparison to 2 replacement donors [Table/Fig-3]. Maximum number of positive TTIs were found in the age group of 31-40 years (80) and the least was found to be in the 61-65 age group (02) [Table/Fig-4]. Out of the total 222 positive donors, 96.40% (214) were males and 3.60% (8) were females. No donor was found positive for malaria. HbsAg positive cases were found to be the most [Table/Fig-5]. Out of 222 TTI positive cases, highest number was for HbsAg i.e., 75.22% (167) followed by syphilis i.e., 9.90% (22). There were 8.55% (19) HCV positive case and found to be more than that of HIV 6.30% (14). No cases of malaria were found [Table/Fig-6]. A total of 222 TTI positive cases were found as four donors showed double positivity so total TTI positive donors were found to be only 218, out of which 210 were males and 8 were females [Table/Fig-7]. Double positivity was found in two donors for HbsAg and HCV. In one donor it was found for HbsAg and VDRL and in another, for HbsAg and HCV [Table/Fig-8]. R square value was calculated to determine the trend of HBsAg, HCV, HIV, malaria, and syphilis over the study period [Table/Fig-9a-d].

Year	Voluntary	Percentage (%)	Replacement	Percentage (%)	Total
2017	4944	98.53	74	1.47	5018
2018	5029	98.70	66	1.29	5095
2019	5727	99.54	26	0.46	5753
2020	3998	100	00	00	3998
Total	19698	99.17	166	0.83	19864

[Table/Fig-1]: Distribution of blood donors in study population year wise.

Year	Male	Percentage (%)	Female	Percentage (%)	Total
2017	4691	93.48	327	6.52	5018
2018	4785	93.91	310	6.09	5095
2019	5219	90.71	534	9.29	5753
2020	3712	92.84	286	7.16	3998
Total	18407	92.66	1457	7.34	19864

[Table/Fig-2]: Distribution of gender in blood donors in study population year wise.

Year	TTI Positive voluntary (%)	TTI Positive replacement (%)	TTI Negative voluntary (%)	TTI Negative replacement (%)	Total
2017	54 (1.07)	1 (0.01)	4890 (97.44)	73 (1.45)	5018
2018	62 (1.21)	0	4967 (97.48)	66 (1.29)	5095
2019	53 (0.9)	1 (0.01)	5674 (98.62)	25 (0.43)	5753
2020	47 (1.17)	0	3951 (98.82)	0	3998

[Table/Fig-3]: Prevalence of TTIs among the voluntary and replacement blood donors.

Age (In years)	HBsAg	HCV	HIV	Syphilis	Malaria	Total
18-20	8	0	2	1	0	11
21-30	39	5	3	9	0	56
31-40	60	6	5	9	0	80
41-50	44	6	3	0	0	53
51-60	15	1	1	3	0	20
61-65	1	1	0	0	0	2

[Table/Fig-4]: Age-wise distribution of reactive TTIs.

TTI	Male	Percentage (%)	Female	Percentage (%)	Total
HBsAg	161	96.40	6	3.60	167
HCV	18	94.73	1	5.27	19
HIV	13	92.85	1	7.15	14
Syphilis	22	100	0	-	22
Malaria	0	-	0	-	0
Total	214	96.40	8	3.60	222

[Table/Fig-5]: Distribution of blood donors with TTIs according to the gender.

Year	HBsAg (%)	HCV (%)	HIV (%)	Syphilis (%)	Malaria	Total
2017	37 (64.91)	8 (14.04)	4 (7.01)	8 (14.04)	0	57
2018	50 (80.65)	5 (8.06)	3 (4.83)	4 (6.45)	0	62
2019	45 (81.82)	3 (5.45)	4 (7.27)	3 (5.45)	0	55
2020	35 (72.92)	3 (6.25)	3 (6.25)	7 (14.58)	0	48
Total	167 (75.22)	19 (8.55)	14 (6.30)	22 (9.90)	0	222

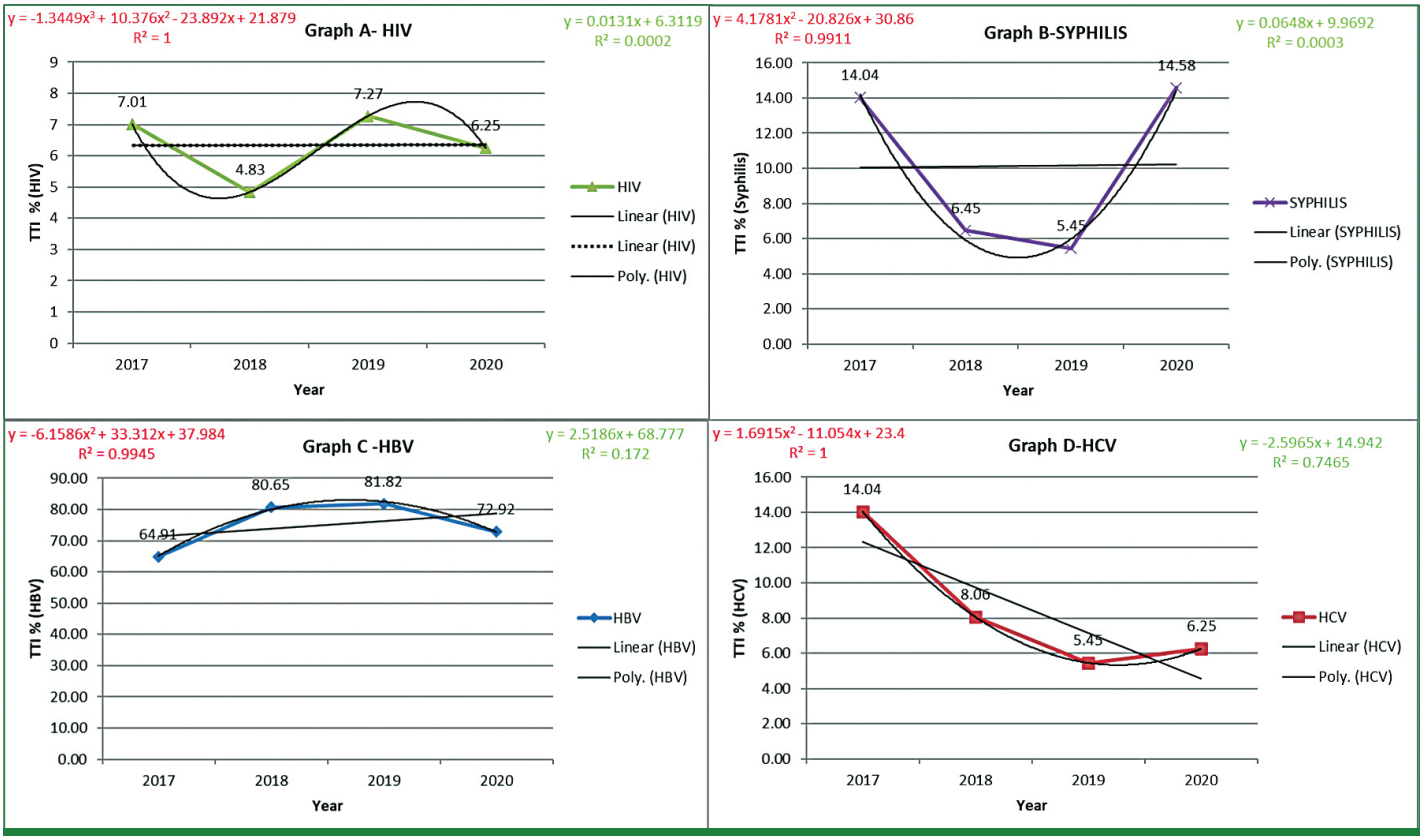
[Table/Fig-6]: HBsAg, HCV, HIV, Malaria, and Syphilis prevalence among study population year wise.

Year	Male	Percentage (%)	Female	Percentage (%)	Total
2017	54	98.18	1	1.82	55
2018	60	96.77	2	3.23	62
2019	50	92.59	4	7.41	54
2020	46	97.87	1	2.13	47
Total	210	96.34	8	3.66	218

[Table/Fig-7]: Distribution of gender in the TTI positive blood donors in study population year wise.

Year	Double positivity	Total
2017	HBsAg and HCV (38/M) HBsAg and VDRL (23/M)	2
2018	---	--
2019	HBsAg and HIV (50/M)	1
2020	HBsAg and HCV (41/M)	1
Total		4

[Table/Fig-8]: Double positive cases.



[Table/Fig-9]: Trends in the prevalence of HIV, HbsAg, HCV and syphilis among blood donors.
Graph A: As the R-square value for Linear trend (Written in Green) is very small that is 0.0002 and the R-square value for non linear trend (Written in red) is 100%. The negative and positive coefficient values indicating increase and decrease in the HIV cases. It shows that HIV cases are following non linear trend over the year; Graph B: As the R-square value for Linear trend (Written in Green) is very small that is 0.0003 and the R-square value for non linear trend (Written in red) is 0.9911 (99.11%) with positive coefficient (0.06 (Almost 0) in Linear and -20.826 in non linear trend equation) value of X (Time). It shows that Syphilis cases have decreased over the time upto 2019 and then suddenly increased in 2020. The R-Square in non linear is 99.11 > 0.0003 (R-Square of linear) indicates that non linear equation represents better the data on time. It shows that Syphilis cases are following non linear trend over the year; Graph C: As the R-square value for Linear trend (Written in Green) is very small that is 0.172 and the R-square value for non linear trend (Written in red) is 0.9945 (99.45%) with positive coefficient (2.52 in Linear and 33.312 in non linear trend equation) value of X (Time). It shows that HBV cases have increased over the time upto 2019 and slightly decreased in 2020. The R-Square in non linear is 99.45 > 0.172 (R-Square of linear) indicates that non linear equation represents better the data on time; Graph D: As the R-square value for Linear trend (Written in Green) is 0.7465 and the coefficient value for the X (Time) is negative indicates that number of cases decreases with respect to time but has increase in year 2020. Therefore, we checked with non linear trend (Written in red) here we got R-squared as is 1.00 (100%). It shows that HCV cases can be better represented by non linear trend over the year.

DISCUSSION

The strategies to prevent the spread of blood borne infections have been extremely effective but transmission still occurs. The reason behind this was primarily the inability of the current tests to detect the disease in the pre seroconversion or 'window' phase of their infection. Other reasons for the same are unbearable cost of screening, lack of funds and trained personnel in charitable institutes, mutant or variant viruses, non seroconverting chronic or immune-silent carriers and inadvertent laboratory testing errors [13].

The first World Health Assembly resolution (WHA28.72), 30 years ago discussed the major subject of safety of blood, fair access to safe blood and its products. They also discussed the safe and rational use of blood and blood products. This remains to be a major concern throughout the world. The challenges of insufficient and scarce access to safe blood transfusion were addressed by the Blood Transfusion Safety team at WHO headquarters where a 'Global Consultation on Universal Access to Safe Blood Transfusion' was organised on 9-11 June 2007 in Ottawa, Canada. The policies drawn during that period are now being implemented throughout the world. Certain recommendations were also made for the development of the WHO Global Strategic Plan for Universal Access to Safe Blood Transfusion 2008-2015 [10].

The finding of various studies conducted in different parts of the world with the present study is showed in [Table/Fig-10] [5,7,12-18]. The seroprevalence rate for HIV in present study was higher than studies done by Fernandes H et al., and Sehgal S et al., even though the study sample was similar in these studies [13,14]. The seroprevalence rate for HbSAg in present study was higher than studies done by Fernandes H et al., and Patel PJ, [13,18]. No positive cases of malaria were reported in the present study. This was similar to other studies [5,7,12,15-18]. The study conducted by Naik VSS et al., showed a lower prevalence of syphilis than present study [5]. Studies done by Fernandes H et al., Patel PJ, were comparable with the present study for HCV Prevalence [Table/Fig-10] [13,18].

Sr. No.	Done by	Place	Duration	Total donors	Male	Female	HIV (%)	HBsAg (%)	HCV (%)	Syphilis (%)	Malaria (%)
1	Naik VSS et al., [5]	Government Medical College, Anantapuram, Andhra Pradesh, India	January 2014 to December 2018	54937	33486 21046 (replacement donors)	405	0.23	1.82	0.31	0.04	-

2	Teklemariam Z et al., [7]	Harar blood bank in Harari regional state, Eastern Ethiopia	2008 to 2015.	11,382	9403	1979	3.8	4.7	0.7	1.3	-
3	Pallavi P et al., [12]	JSS Hospital, Mysore, India	2004 to 2008	39,060	38,215	845	0.44	1.27	0.23	0.28	-
4	Fernandes H et al., [13]	Father Muller Medical College Hospital, Mangalore, India	July 2007 to June 2009.	9,599	9,357	242	0.06	0.34	0.06	0.11	0.01
5	Sehgal S et al., [14]	Blood Bank of G.B Pant Hospital, Andaman and Nicobar Islands Institute of Medical Sciences, Port Blair, India	April 2013 to March 2016	12118	11756	362	0.06	1.05	0.12	0.24	0.69
6	Negash M et al., [15]	South Gondar District blood Bank, Northwest Ethiopia	January 2017 to February 2018	310	198	112	2.6	5.8	4.2	-	-
7	Chandekar SA et al., [16]	B Y L Nair Charitable Hospital, Mumbai, Maharashtra, India	January 2007 to December 2011	76653	70363	6290	0.26	1.3	0.25	0.28	-
8	Mandal R et al., [17]	Department of Blood bank, North Bengal Medical College and Hospital, Darjeeling, West Bengal, India	2010-2012	28364	25517	2847	0.42	1.24	0.62	0.65	-
9	Patel PJ, [18]	Blood Bank, GMERS Medical College, Gandhinagar, Gujarat, India	2007-2013	15368	14304	1064	0.14	0.38	0.06	0.14	-
10	Present study	MGM Medical College and Hospital, Navi Mumbai, India	January 2017 to 2020 December	19864	18407	1457	0.07	0.84	0.09	0.11	-

[Table/Fig-10]: Comparison of Transfusion Transmitted Infections (TTIs) prevalence rate with other studies [5,7,12-18].

Limitation(s)

This study only made a comment on the prevalence of HIV, HBsAg, HCV, syphilis, and malaria. No other TTIs were considered. Occult hepatitis cannot be commented upon as Anti-HBc IgM is not tested currently in our centre. The study was limited to one blood centre, narrowing the sample size. Observations cannot be generalised on the limited data collected as the female donors were less in number.

CONCLUSION(S)

Maximum number of donors was voluntary. Prevalence of hepatitis B was highest followed by syphilis, HIV and HCV and malaria. There was a non linear trend in these TTIs. Prevalence was found to be more in male donors. Multiple examples can be sited from the literature to signify the importance of proper testing for TTIs and its implications in transfusion medicine. Voluntary donors should be encouraged, and thorough pre donation counselling should be provided to inform them of the donation window and infection risk. To supply safe blood and protect recipients, strict adherence to donor selection criteria and the inclusion of sensitive tools for TTI detection should be advocated.

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PARTICULARS OF CONTRIBUTORS:

1. Assistant Professor, Department of Transfusion Medicine, MGM Medical College, Navi Mumbai, Maharashtra, India.
2. Junior Resident III, Department of Transfusion Medicine, MGM Medical College, Navi Mumbai, Maharashtra, India.
3. Professor and Head, Department of Transfusion Medicine, MGM Medical College, Navi Mumbai, Maharashtra, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Dr. Shweta Wasudeo Dhote,
Flat No. 701, Bhairav Signature, Sector 30, 31, CBD Belapur,
Navi Mumbai-400614, Maharashtra, India.
E-mail: shwetadhote02@gmail.com

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- Manual Googling: Jun 15, 2021
- iThenticate Software: Jul 07, 2021 (10%)

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