ORIGINAL RESEARCH

Seroprevalance of Transfusion Transmitted Infections among Blood Donors at a Tertiary Care Teaching Institution in North India

[1]Dr. Abhitesh Badhan, [2]Dr. Rajbir Kaur Cheema

[1]Senior Resident, Department of Transfusion Medicine, Maharishi Markandeshwar Institute of Medical Sciences and Research, Mullana, Ambala, Haryana, India
[2]Assistant Professor, Department of Transfusion Medicine, Maharishi Markandeshwar College of Medical Sciences and Research, Sadopur, Amabala, Haryana, India

Corresponding Author
Dr. Rajbir Kaur Cheema
Assistant Professor, Department of Transfusion Medicine, Maharishi Markandeshwar College of Medical Sciences and Research, Sadopur, Amabala, Haryana, India, Email: cheemarajbir50@gmail.com

Received: 12 March, 2023 Revised: 4 April, 2023 Accepted: 17 April, 2023

ABSTRACT

Introduction: Transfusion transmissible infections (HIV, HBV, HCV, syphillis and malaria) are among the major threats to the safe blood supply for the patients requiring blood transfusions. Seropositivity rate of TTIs among blood donors is a useful source of information to check their seroprevalance in a community which can give us accurate estimates of risk of TTIs, essential for monitoring safe transfusion services. Aim: To estimate the seropositivity of Human Immunodeficieny virus (HIV 1 & 2), Hepatitis B surface Antigen (HBsAg), Hepatitis C virus (HCV), Syphilis and Malaria among blood donors of a tertiary care teaching institution in north India. **Materials and methods:** This retrospective study was done from January 1 2022 to March 31, 2023 in Department of transfusion Medicine at a tertiary care teaching institution of north India. The results of serologic markers for Transfusion transmissible infections (HBsAg, anti-HCV, anti-HIV, syphilis and malaria) of all blood donations (both voluntary and replacement) at our hospital were collected from departmental records. Collected data was tabulated in Microscoft Excel and results were expressed as percentage. **Results:** Out of total number of 6505 donos, male donors were 6452, while 53 were female donors. 4213 donors out of 6505(64.76%), were repeat donors. There were total 160 seropositive donors, all of whom were male (100%) and 136 (85%) were replacement donors. There were no female reactive donors (0%). The highest number of TTIs were seen in 26 to 35 age group (41.87%), followed 36 to 45 years old (26.87%). The overall seropositivity rate of TTIs was 2.46% (160/6505). There were 50 donors who tested positive for HBV, 48 for HCV, 11 for HIV, 51 for Syphilis, and none for Malarial parasite. **Conclusion:** The current study found a low level of TTI seroprevalence in donor pool, indicative of a low overall level of TTIs in the population. Stringent donor screening and recruiting more of voluntary blood donors is need of hour for providing safe transfusion services.

Keywords: Seropositivity, Transfusion, Transmissible Infections, Blood Donors.

INTRODUCTION

The donation of blood and other products derived from blood is an essential part of modern medical practice. The administration of timely, sufficient, and risk-free blood transfusions is a practice that saves lives. An unsafe blood transfusion not only raises the likelihood of TTIs, but also the danger of potentially fatal consequences [1]. There is always a worry about the safety of blood due to the fact that the spread of infectious illnesses via blood donation is conceivable. Human immunodeficiency virus (HIV 1 & 2), hepatitis B virus (HBV), hepatitis C virus (HCV), syphilis, malaria, toxoplasmosis, brucellosis, and a few viral illnesses such as herpes virus, cytomegalovirus, and Ebstein Barr virus are examples of the transmissible blood-borne pathogens that may be acquired by blood donation [1].

Every unit of blood has a 1% risk of complications connected with the transfusion, including transfusion-transmitted infections (TTIs). HIV and hepatitis are the two infectious diseases that pose the greatest risk to human life. The incidence of TTIs in the population of India is still unclear due to the following reasons: lack of knowledge, the absence of surveillance systems, the unaviabilty of accurate screening tests, and restricted access to health services [2].

Evidence of TTI was initially seen after blood transfusion in the late 1940s, and up until 1970, blood

centres tested solely for hepatitis and syphilis, while being aware of additional illnesses [3]. One of the most difficult difficulties faced in the field of transfusion medicine is preventing the spread of infectious illnesses like these via the use of blood donations [4]. When compared to blood supplied by voluntary non-remunerated donors, the risk of transfusion-transmissible infections (TTIs) is much greater for blood donated by family members or replacement donors. Paid or professional blood donors had the greatest frequency and prevalence of transfusion-transmitted infections [5]. Donors who give blood on a voluntary basis are the ones who pose the least risk since they are more likely to be health conscious and are driven by altruism when it comes to helping patients in need and are getting tested for TTI after every blood donation in a licensed blood centre. Pre-transfusion testing for HBV, HIV, HCV and Syphilis is mandatory according to recommendation made by the World Health Organization (WHO) [6]. The infectious markers for these TTIs include anti HIV (1 and 2) antibodies, hepatitis B surface antigen (HBsAg), anti-hepatitis C virus antibodies, and malaria antigens, such as histidine rich protein (HRP) and pan-aldolase. VDRL (venereal disease research laboratory)/RPR (rapid plasma reagin) test is done for anticardiolipin antibodies. According to the National AIDS Control Organization (NACO) guidlines [7], every positive test result should result in the discarding of the entire blood unit as well as any blood components that came from that unit. The epidemiology of these illnesses in the population may be inferred from an analysis of the data about seropositivity[8]. The most reliable supply of blood for the transfusion system comes from donors who give their own blood voluntarily and for no financial compensation [9]. Because there are fewer voluntary donations in India and decentralised blood transfusion services, the quality of the blood supply may be at risk [10]. The present study was carried out with the aim to look for the seroprevalence of TTI infectious markers among the blood donors of a tertiary care institution based blood transfusion service set up in north India.

METHODOLOGY

This research was conducted using a retrospective approach in the Department of Transfusion Medicine of a tertiary care teaching institution of north India between the months of January 2022 and March 2023, covering a span of 18 months. Retrospectively TTI screening data of all blood donors was retrieved from records available in the department. Both voluntary and replacement donations of whole blood were accepted at the current blood centre. All blood donors went through a thorough clinical history and physical examination before being approved for blood donation in accordance with the standard operating procedures (SOPs) of the department and the national guidelines for the selection and Referral of blood donors [11]. Each donor was given a one-of-a-kind donor number, and information such as their name, age, gender, date of birth, occupation, marital status, and phone number was recorded for each one. Before donating blood, each potential donor was asked to provide their written informed consent.

A questionnaire, present in the department of transfusion medicine in accordance with the annexure of the Guidelines for Blood Donor Selection and Blood Donor Referral [11], was distributed to the donors. For the convenience of the patient, the questionnaire was available in both English and the donor's native language (hindi). It included information about the donor's general health, history of previous blood donations or transfusions, history of ailments such as allergy, renal diseases, endocrine diseases, heart diseases, high/low blood pressure, sexually transmitted diseases, current or past febrile illness, weight loss, infections such as tuberculosis and malaria, unusual or excessive bleeding, drug history, tattoo, piercing and blood type. At the location of the venipuncture, an examination was performed to look for any signs of drug misuse or any skin lesions. During the blood collection process, correct sterilizing procedures were carried out, and blood units were kept in the refrigerator at a temperature between 2-6°C.

Donors had to be physically fit, between the ages of 18 and 60, having a hemoglobin level of more than 12.5 gm/dL for both genders, and weigh more than 45 kg were eligible to donate blood.

Donors with a history of jaundice or asthma, high risk behaviors such as a history of unsafe sexual encounters or drug abuse, and donors with a history of HIV, HBV, HCV and syphilis were not allowed to donate blood. Other exclusion criteria included a weight of less than 45 kilograms, an age of less than 18 years, anemia (Hb<12.5 gm%), donors who appear to be unhealthy or malnourished, and donors who had a history of jaundice or asthma.

According to the Guidelines for Blood Donor Selection and Referral published by the Government of India [11], donors who had a history of dental treatment were barred from giving blood for a period of six months, donors who had tattoo and piercings were barred from giving blood for a period of twelve months, and donors who had unusual or excessive bleeding were barred from giving blood forever. For every donor, a thorough history and clinical assessment were performed by transfusion Medicine specialist in order to screen out any potential paid or professional donors. The screening of TTIs was done using pilot tubes that were taken during blood donation.

A standard methodology according to departmental standard operating procedures was followed to separate the serum of blood samples taken in pilot tubes following blood donation to analyze them for TTI testing. Any sample that tested sero-positive for any of the five TTIs in the first round of testing were

subjected to further testing in round two to validate the positive result. From January 1, 2022 to July 15, 2022 blood samples were tested through an Enzyme-Linked Immunosorbent Assay (ELISA) assay of the third (HBV and HCV) and fourth generation (HIV), completed with an automated ELISA washer and reader, in order to check for testing of HIV, HBsAg. Fourth generation Microlisa HIV Ag & Ab (J.MITRA) was used to screen for HIV 1 & 2. Third generation Hepalisa (J. Mitra) for HBsAg testing and HCV Microlisa (J. Mitra) were used for HCV testing. From July 16, 2022 onwards TTI testing platform was shifted to Enhanced Chemilumiscence Immunoassay (ECi) by Ortho clinical diagnostics for the detection of anti-HCV, HBsAg and anti- HIV 1 & 2. S per the documentation provided by the kit manufacturer, the controls, protocol, and cut-off values for positive and negative outcomes were computed. The Syphilis Carbogen regent pack test (Coral Clinical System) a rapid chromatographic immunoassay was used for detecting antibodies to Treponema Pallidum for all blood samples. Malaria was tested by the use of the Rapid Antigen Testing by Card technique for the Plasmodium species (P. falciparum/P. vivax/P. malariae/P.ovale) malaria parasite with the use of the Advantage Mal Card (J Mitra). Before labelling any of the seropositive samples as positive, they were all put through two rounds of testing according to departmental SOPs. The percentage of seroprevalance of TTIs was determined by dividing the number of seropositive cases by the total number of annual blood donation. In accordance with the standards governing the handling of biological waste [12], seropositive units were discarded.

STATISTICS ANALYSIS

The information gathered was put into a spreadsheet created in Microsoft Excel. Rates, ratios, and percentages were used to represent the categorical data that was collected.

RESULTS

There were a total of 6592 people who donated blood in the study period, out of which 6505 donors were suitable for donation and 87 donors were excluded from blood donation during donor screening process by the doctor as they did not meet the inclusion criteria. Each and every donor donated blood out of their own free will. The total number of male donors came to 6452, while the number of female donors was 53. There were a total of 4213 donors out of 6505, or 64.76 percent, who had prior experience donating blood. There were a total of 160 seropositive donors, all of whom were male (100%). There were no female seropositive donors (0%). The highest number of TTIs were found in those aged 26 to 35 years old (41.87%), followed by people aged 36 to 45 years old (26.87%) as indicated in table 4-6. Year-by-year distribution of TTI positivity has shown in [Table1]. The frequency of seropositivity was greater in men as compared to females among those who tested positive for TTIs, which contributed to the overall seropositivity rate of TTIs being 2.46% (160/6505). As shown in [Table 2], there were 48 donors who tested positive for HCV, 11 donors who tested positive for HIV, 51 donors who tested positive for Syphilis, and nil who tested positive for Malaria. There were 50 donors who tested positive for HBV. Within the scope of study, there was not a single instance of any TTI being co-infected with another. Donors who tested positive for any of the five TTIs, were informed telephonically and encouraged to visit and meet expert medical staff at the department of transfusion medicine. In order to get insight into the lifestyles of reactive blood donors, counselling was conducted with them. During the interview, reactive blood donors were questioned about their histories of prior blood transfusions, jaundice, family history, sexual practices and high-risk behaviors in an effort to determine what factors contribute to TTI reactivity. It was discovered that the majority of donors who tested positive for HIV and syphilis engaged in sexual behavior associated with a high risk, but the majority of donors who tested positive for HBV and HCV did not give any significant history.

DISCUSSION

In addition to ensuring that patients get safe blood transfusions, screening blood for TTIs gives statistics on the incidence of these illnesses in otherwise healthy individuals [13]. When it comes to policymaking, the government may benefit from reliable epidemiological statistics on the illness prevalence in the population [14]. As Busch MP et al. [15] explains, it is feasible to ensure the safety of the blood supply and calculate the efficacy of the screening measures that are now in place. The high prevalence of asymptomatic TTI carriers and the high volume of blood donations received during the window period both provide significant difficulties to the integrity of the blood supply. HBV is the most common cause of hepatitis spread via the bloodstream through the skin, and it is linked to a prolonged carrier status as well as chronic liver disease. In the majority of the studies [16-18], those with a history of TTI had the greatest HBV seropositivity. In our study also, the seropositivity rates for HBV (0.77%) and Syphilis (0.78%) were found to be higher, whilst the rates for HIV, Malaria, and HCV were found to be lower. An Indian research revealed that the percentage of people who tested positive for HBV in 1996 was 1.55%, but by 2002, that number had dropped to 0.99% [19]. Other studies conducted in India [20-22] found that the frequency of HBV antibodies varied from 1.86% to 4%.

Table 1: Year wise distribution of seropositivity of TTIs

Time period	Total Number of Donations	Male Donors	Female Donors	Voluntary	Replacement	First time	Repeat	HBV	HCV	HIV	Syphilis	Malaria	Total TTI reactive donors	% (seroprevalance)	Reactive Male Donors	Reactive Female Donors	Reactive Voluntary	Reactive Replacement	First time	Repeat
JAN 2023-MARCH-23	1551	1537	14	442	1109	571	980	11	6	0	15	0	**32**	2.06	32	0	3	29	20	15
2022 (JAN 2022-DEC 2022)	4954	4915	39	1223	3731	1721	3233	39	42	11	36	0	**128**	2.58	128	0	21	107	61	67
Total	6505	6452	53	1665	4840	2292	4213	50	48	11	51	0	160	2.46	160	0	24	136	81	82

Table 2: Seroprevalance data of TTIs among blood donors

TTI	Number of Donors	Percentage
HBV	50	0.77
HCV	48	0.73
HIV 1 & 2	11	0.16
Malaria	0	0
Syphylis	51	0.78

Table 3: Demographic data of blood donors

	Voluntary	Replacement	First time	Repeat
HBV	12	38	28	22
HCV	5	43	29	20
HIV 1 & 2	1	10	3	9
Syphilis	6	45	21	31
Malaria	0	0	0	0
Total	24	136	81	82

Table 4: Age distribution of sero-positive blood donors in 2023 (January to March)

Age Group	2023			
	HBV	HCV	HIV	Syphillis
18-25	4	1	0	3
26-35	4	1	0	7
36-45	2	3	0	4
>45	1	1	0	1

Table 5: Age distribution of sero-positive blood donors in 2022 (January to December)

Age Group	2022			
	HBV	HCV	HIV	Syphillis
18-25	14	13	1	3
26-35	14	22	6	13
36-45	9	6	2	17
>45	2	1	2	3

Table 6: Age distribution of all sero-positive blood donors

Age Group	2023	2022	Total
18-25	8	31	39
26-35	12	55	67
36-45	9	34	43
>45	3	8	11

It is arguable that the transmission of HIV via blood transfusions and the subsequent outbreak of the acquired immunodeficiency syndrome (AIDS) pandemic that was connected with transfusions have fundamentally altered the practice of transfusion medicine over the course of the last few decades. The aetiological agents are the HIV-1 and HIV-2 viruses. There have been reports that the prevalence of HIV in India ranges anywhere from 0.2 to 1% [20]. After the first, second, and third generations of ELISA, the fourth generation of ELISA was developed with the goal of shortening the window time to between 15 and 18 days. This test, which detects both p24 antigen and antibody to HIV, is currently used as a screening test for HIV [23]. Although the NAT is not a mandatory screening test for TTIs in accordance with the Drug and Cosmetic Act [24], it is employed in some centers in India, to lower the residual risk of borderline and seronegative donations. Because of the implementation of the viral NAT system, the time it takes for successful detection has been cut down to between 5 and 11 days, which has considerably decreased the residual risk of viral transmission. In the year 2013, the NACO stated that the seroprevalence of HIV among blood donors in India was 0.27% [25]. Transmission through blood transfusion is the third most common route of HIV transmission in India. 0.3% of people in the general population have HIV antibodies [26], which indicates that they are infected with HIV. The HIV seroprevalence found in this investigation was 0.16%. The seroprevalence that was found in this research is much lower than that found in earlier studies from different regions of India [20,27].

The most common method of HCV transmission is via blood contact. Acute HCV infections account for around 20% to 40% of all cases, but the majority of patients go on to develop chronic HCV. Individuals infected with HCV have a larger risk of developing cirrhosis and hepatocellular cancer in the long term compared to patients infected with HBV. This increased risk is related to the fact that HCV infections tend to be more severe. Depending on whatever study you look at, the prevalence of HCV in India might be anywhere from 0.4 to 1.09% [20]. The seroprevalence for Hepatitis C was found to be 0.73% in this research, which is a lower number when compared to the study that was conducted by Bagga PK and Singh SP [28].

In impoverished nations with limited blood supplies, where the blood is often acquired from family donors and transfused within hours, the risk of transfusion-transmitted syphilis is especially high [29]. The presence of syphilis indicates that the donor is engaged in "high-risk" behavior, which puts them at a greater chance of being exposed to other infectious diseases including HIV and hepatitis [20].

Parasites that cause malaria may live in components for at least a week if they are kept at room temperature or 4°C [30]. Malaria which spreads via blood transfusions is rarely seen and is often caused by asymptomatic carriers [20]. Examination of thick and thin smears taken from the periphery has been the diagnostic technique that has been considered the gold standard. In addition to being a labor-intensive process, this method necessitates the presence of certain technical expertise as well as technicians. As a consequence of this, various quick antigen detection techniques for whole blood have emerged in order to identify the antigen produced by the malaria parasite. Using ELISA, it is possible to identify blood donors at high risk for malaria who only have a partial immunity to the disease. Malaria antibody tests may identify the presence of specific IgG antibodies against Plasmodium falciparum, Plasmodium vivax, Plasmodium ovale, and Plasmodium malariae [31,32].

In the different studies that were conducted in India, blood donors were tested to determine their seroprevalence of HIV, HBV, HCV, Syphilis, and Malaria. Syphilis varies between 0.11% and 1.6%, HIV seroprevalence ranges between 0.3% and 0.60%, HBV seroprevalence ranges between 0.99% and 3.44%, HCV seroprevalence ranges between 0.28% and 1.2%, and malaria seroprevalence is between 0% and 0.05%. When compared to replacement donation, these studies found that voluntary blood donation was associated with a lower risk of transfusion-transmitted infections (TTIs) and was recommended for safe transfusion services . Replacement donors had a higher prevalence of TTIs than voluntary donors [4,22,29].

According to a study by Fernandes H et al., the prevalence of TTIs in total blood donors was 0.6%. The prevalence of Hepatitis B was highest (0.34%), followed by the prevalence of Syphilis (0.11%), which is comparable to the current research. According to their findings, the prevalence of HIV (0.06%), HCV (0.06%), and malaria (0.01%) respectively. It was also shown that male replacement donors had a higher prevalence of TTIs [33]. In the research conducted by Leena MS and Mohd S., there were a total of 6939 blood donors; out of these donors, 94 (1.35%) were found to be positive for sero-markers of TTIs [26]. In terms of the various TTIs, the proportion of blood donors who had Hepatitis B was the greatest (0.77 percent), followed by those who had HIV (0.16 percent), HCV (0.73 percent), malaria (0 percent), and

syphilis (0.78 percent). According to the findings of a number of researches [4,13,26,34,35], the seroprevalence of hepatitis B among blood donors was much greater than that of HIV, HCV, syphilis and malaria.

The following researchers conducted investigations on TTI: Mandal R and Mondal K, Leena MS and Mohd S, Makroo RN et al., Kaur G et al., NACO and Sethi B et al. [16,26,27,36-38]. The results of these studies are compared in [Table 7]. The majority of these studies demonstrate the higher incidence of HBV seropositivity compared to other TTIs. The varied percentage of voluntary and replacement blood donations, as well as the efficiency of donor selection, all contribute to the fact that the levels of seropositivity might vary widely from one study to the next. According to the findings of this study, the prevalence of HBV has fallen significantly over the course of the last few years. On the other hand, there has been an uptick in the number of people getting syphilis during the last several decades. The general incidence of TTIs increased during most of the years, with the notable exception of 2022 and 2023, when there was a significant drop. In the present study, maximum TTIs were seen in the age group of 26-35 years (41.87%) which is similar to study done by Mandal R and Mondal K [16].

Table 7: Comparison of seroprevalance (in percentages) of blood donors in different studies.

Author	HBV	HIV	HCV	Syphilis	Malaria
Kaur G etal.,[36]	1.7	0.6	0.8	0.7	0
Makroo RN etal.,[27]	1.18	0.24	9.87	0.43	0
Mandal R and Mondal K,[16]	1.24	0.42	0.62	0.65	0.004
NACO[37]	1.09	0.19	0.28	0.04	0.039
Leena MS and Mohd S,[26]	0.71	0.27	0.14	0.10	0.12
Sethi B etal.,[38]	0.63	0.19	0.20	0.02	0
Present study	0.77	0.16	0.73	0.78	00

The reason of lower TTI seropositivity in our study as compared to study by Makroo RN et al (27) and Kaur G et al (36) could be due to the reason that this study was done in a academic institute where before donating blood awareness about TTIs were given to blood donors by experts. The current research indicates that there is a small pool of female donors which indicates there should be more of an effort made to promote donation from female donors. Over the time it has been observed that it is a common practice for professional or replacement donors to hide their medical history, which creates a significant risk for the integrity of the blood supply. In light of the fact that replacement donors have been shown to have a greater prevalence of seropositivity, it is imperative that individuals be motivated to donate voluntarily. TTIs cannot be decreased to zero for the following reasons: a lack of tests that are sensitive to 100 percent of the population, the availability of new infectious agents, inability of the test to detect the disease in the 'window' period of infection, immunologically variant viruses, immune-silent carriers and inadvertent laboratory testing errors. A higher frequency of testing will lead to the postponement of safe donors as a consequence of an increase in the number of false positive findings and greater costs associated with testing the patient.

CONCLUSION

The current study found a low level of TTI seroprevalence in blood donors, which is indicative of a low overall level of TTIs in the population. Blood transfusion remains a risk factor for the spread of blood-borne infections. So, for safe blood transfusion practices we need to enure implemention of strict pre-donation donor screening, accurate TTI screening tests along with rational use of blood and blood products on the patient end. The study also reinforces that voluntary donors are safer than the replacement donors, hence recruitment and retention of more repeat-regular voluntary donors will be a major step towards safe blood transfusion services.

ACKNOWLEDGEMENT

The authors thank all donors who donated blood in the need of hour for the patients. We would also like to thank technical and non-technical staff of Department of Transfusion Medicine of Maharishi Markandeshwar Institute of Medical Sciences & Research (MMIMSR), Mullana, Ambala (Haryana) for their active cooperation.

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Source of Funding: None

Conflict of Interest: None declared