

# Comparative Study of Seropositivity of Mandatory Blood Transfusion Associated Diseases between Voluntary and Replacement Donors

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## ABSTRACT

### BACKGROUND

Every blood transfusion is associated with 1 % chance of transfusion associated problems including transfusion transmitted blood-borne infections to its recipient. The major globally prevalent transfusion transmitted infections are human immunodeficiency virus, hepatitis B virus, hepatitis C virus, syphilis and malaria parasite. We wanted to compare safety of blood among replacement and voluntary donations by comparing the prevalence of transfusion-transmissible infections among them.

### METHODS

All donors were screened by enzyme-linked immunoassay for five transfusion transmissible infectious agents - human immunodeficiency virus, hepatitis B virus, hepatitis C virus and syphilis by collecting plasma from the pilot tube attached to the blood bag. Malaria was tested from whole blood sample.

### RESULTS

A total of 24,491 donors was included in the study. Among them 21,090 (86.11 %) were replacement and 3,401 (13.89 %) were voluntary donors. Out of 24,491 donors, 560 (2.29 %) units tested positive. Hepatitis B virus (hepatitis B surface antigen) is found to be the most prevalent transfusion transmitted infection among both replacement donations and voluntary donations.

### CONCLUSIONS

There should be more voluntary donations to achieve safer blood transfusion practices as self-deferral by donors with high risk condition is the most effective way to reduce prevalence of transfusion transmitted infections.

### KEYWORDS

Enzyme-Linked Immunoassay, Hepatitis C Virus, Hepatitis, Replacement Donors, Transfusion Transmitted Infections, Voluntary Donors

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**BACKGROUND**

Transfusion services form a very important part of every health care system. It is most essential for each nation to provide adequate supply of safe blood for transfusion as morbidity and mortality associated with transfusion-transmitted infections (transfusion-transmitted infections) reveal long-term effects on the recipients, their families, and the community. Every blood transfusion is associated with 1 % chance of transfusion associated problems including transfusion transmitted blood-borne infections to its recipient.<sup>1</sup> Apparently, healthy donors can also transmit an infection during asymptomatic phase, further increasing the prevalence of various infections in general population. Blood transfusion service is an integral part of our healthcare system ensuring safe, adequate, accessible and efficient blood supply at all levels.

Transfusion transmitted infections can be caused by various infective microorganisms, which may be present in the blood being transfused. The major globally prevalent transfusion-transmitted infections are caused are human immunodeficiency virus, hepatitis B virus, hepatitis C virus, syphilis (*treponema pallidum*) and malaria parasite. In minority cases, viral infections such as cytomegalovirus, herpes virus, and Epstein-Barr virus along with toxoplasmosis and brucellosis may be transmitted.<sup>2</sup> Screening is done routinely for the prevention of these infections in all transfusion centres. In India, it is mandatory to screen donors for human immunodeficiency virus 1 and 2, hepatitis B virus, hepatitis C virus, syphilis, and malaria, as per the guidelines of the ministry of health and family welfare, under the Drug and Cosmetic Act 1945.<sup>3</sup>

Availability of newer and more-sensitive screening tests has significantly reduced incidence of transfusion-transmitted infections in most developed countries, on the other hand, in most of the developing countries there is increasing prevalence and incidence of these infections, due to poor health infrastructure, lack of health awareness among people, and failure to implement strict norms of screening.<sup>4</sup> Majority of developing countries are still dependent on replacement donations. According to the World Health Organization (WHO) report, risk of transmitting transfusion-transmitted infection was found to be higher in countries which are dependent on family / replacement or paid donors.<sup>5</sup> The World Health Organization developed a plan of action to achieve 100 % voluntary non remunerated blood donation throughout the world to reduce the risk of transfusion-transmitted infections and provide adequate safe blood for transfusion.<sup>6</sup> So with continuous improvement in donor selection, sensitive screening procedures and effective inactivation methods can ensure the reduction of transfusion-transmitted infections.

In India, National Blood Policy has been formed which focuses on phasing out replacement donors and to achieve 100 % voluntary blood donation<sup>7</sup> but still replacement donation is major form of collected blood in India. In India majority of blood banks are still dependent on replacement donation to maintain their stock which indicates a non-uniform implementation of blood policy. In 2008, India reported rise in the number of voluntary donors from 3.6

million in 2007 to 4.6 million in a report submitted to the World Health Organization for global data on blood safety.<sup>8</sup> Various studies from different parts of India indicate that many blood banks are still dependent on replacement donors to maintain adequate stock.<sup>9-12</sup>

Though all these strategies have been effective, but transmission of transfusion transmitted diseases still occurs, primarily because of the inability of the test to detect the disease in the 'window' period of infection, immunologically variant viruses, immune-silent carriers and laboratory testing errors.<sup>13</sup> Evaluation of data on the incidence of transfusion transmitted infections among blood donors provides an assessment of accurate estimation of risk of transfusion-transmitted infections, which helps to formulate long term strategies to prevent spread of disease in local population. The present study is a comparative study carried out with aim to analyze safety of blood among replacement donations and voluntary donations by comparing the prevalence of transfusion-transmissible infections in replacement donors and voluntary donors.

**METHODS**

This is a cross sectional study conducted at Transfusion Medicine Department of a Medical College, Uttar Pradesh, India, for duration of 12 months from January 2018 to December 2019. All blood donors were requested to fill a form designed as per the National AIDS Control Organisation guidelines for donor eligibility criteria. Donors with haemoglobin less than 12.5 g % or known seropositive for transfusion-transmitted infection were deferred and excluded from the study group. Informed consent was taken from all donors before blood donation. All apparently healthy donors above 18 years and below 60 years of age, (who fulfilled donor selection criteria) were included in the study. Paid / professional donors were identified and excluded from the study. Donors were divided into voluntary blood donors (VD) who were non-remunerated donors who donated blood on his / her free will and replacement donors (RD) who were apparently healthy donors and were either friends or relatives of the patients and donated blood as per the requirement of their patients.

All donors were screened for five transfusion-transmissible infectious agents human immunodeficiency virus, hepatitis B virus, hepatitis C virus, & syphilis by collecting plasma from the pilot tube attached to the blood bag. Whole blood samples were used for malaria test. enzyme-linked immunoassay test was applied for detecting anti-human immunodeficiency virus-1 and human immunodeficiency virus-2, hepatitis B surface antigen (HBsAg), and anti-hepatitis C virus. All tests were done by enzyme-linked immunoassay technique as per the guidelines provided by the manufacturer. Known positive and negative controls were run with each test. Repeat test was performed for all the positive samples using same enzyme-linked immunoassay test kits. Screening for syphilis was done using syphilis rapid card, it detects TP antibody (IgA, IgM, and IgG) using immune chromatography principle. Test for malaria was done by rapid card test. It is based on the

principle of immunochromatography. It detects the presence of Pan malaria specific pLDH as well as *Plasmodium falciparum* specific histidine rich protein (Pf. HRP-2) Samples that were positive on repeat testing were labelled as positive for respective transfusion-transmitted infection and were placed separately under discarded blood units. Statistical analysis was done using chi square test.

## RESULTS

A total of 24,491 donors were selected in the study. Out of total 24,491 donations, 21,090 (86.11 %) were replacement donations and 3,401 (13.89 %) were voluntary donations and a total of 560 (2.29 %) units were tested positive. Among 21,090 replacement donations 538 units were tested positive and among 3,401 voluntary donations 22 units were tested positive [Table I]. Out of 560 positive units, maximum number of the cases were of hepatitis B virus (hepatitis B surface antigen) (309), followed by hepatitis C virus (110) cases. human immunodeficiency virus, syphilis and malaria comprised of 30, 91, and 20 cases respectively [Table II].

On distributing total positive units of replacement donations, 293 units were hepatitis B surface antigen positive, 104 units were hepatitis C virus positive, 30 units were human immunodeficiency virus positive, 91 units were venereal disease research laboratory test positive and 20 units were positive for malaria [Table II]. Out of 22 positive cases among voluntary donations, 16 were of HbsAg and 6 units were positive for hepatitis C virus. There was no case of human immunodeficiency virus, malaria as well as syphilis [Table III].

On evaluating the seroprevalence of transfusion-transmitted infections among the replacement donors in the present study, HbsAg was found to be most prevalent (1.39 %) followed by hepatitis C virus (0.49 %). The prevalence of human immunodeficiency virus, syphilis and malaria was 0.14 %, 0.43 % and 0.09 % respectively. Among the total voluntary donations most prevalent transfusion-transmitted infection was again HbsAg (0.47 %) followed by hepatitis C virus (0.18 %). In the present study we do not find human immunodeficiency virus, syphilis and malaria positive cases among voluntary donations [Table IV].

Type of Donation	Units Tested Positive	Units Tested Negative	Total
Replacement	538	20,452	21,090
Voluntary	22	3,379	3,401

**Table 1. Total Number of Voluntary and Replacement Donations with Total Positive Units**

(Chi square test statistic- 47.8864, p value < 0.00001 showing result significant at p < 0.05)

Type of Transfusion-Transmitted Infection	Total Number (RD + VD) n = 24491	(%)
Hepatitis B virus	309	1.27
Hepatitis C virus	110	0.45
Human Immunodeficiency Virus	30	0.12
Syphilis	91	0.37
Malaria	20	0.08
<b>Total</b>	<b>560</b>	<b>2.29</b>

**Table 2. Distribution of Transfusion-Transmitted Infections among Total Positive Units**

Type of Transfusion-Transmitted Infection	Replacement Donations n = 21090		Voluntary Donations n = 3401	
	Number	(%)	Number	(%)
Hepatitis B virus	293	1.39	16	0.47
Hepatitis C virus	104	0.49	06	0.18
Human Immunodeficiency Virus	30	0.14	00	0
Syphilis	91	0.43	00	0
Malaria	20	0.09	00	0
<b>Total</b>	<b>538</b>	<b>2.54</b>	<b>22</b>	<b>0.65</b>

**Table 3. Distribution and Comparison of Transfusion Transmitted Infections (transfusion-transmitted infections) among Replacement Donations and Voluntary Donations**

## DISCUSSION

Transfusion of blood and blood products is a life saving measure, but it is also an important mode of transmission of infection to the recipients. Since the starting of blood transfusion, many transfusion-associated problems have occurred including transfusion-transmitted infections. Mandatory testing of all blood units before transfusion is of utmost importance to achieve the target of blood safety. Analysis of transfusion-transmitted infections in blood donors can give a rough estimate of their prevalence in general population, however they are not truly representative of them due to selection bias and exclusion of high risk and paid donors during screening of donors. With every unit of blood, there is 1 % chance of transfusion associated problems including transfusion-transmitted infection.

High sero-positivity rates of transfusion-transmitted infection among replacement donors were noted in comparison to voluntary donors. Replacement donors constituted about 86 % of the total donations, while voluntary donations comprised of only 14 %, similar distribution of replacement donations (85.19 %)<sup>12</sup> and (82.4 %)<sup>13</sup> was reported by other Indian studies. In contrast to our findings, few similar studies from south India (61.2 %)<sup>14</sup> and western India (87 %)<sup>15</sup> reported higher percentage of voluntary donations. This difference could be due to higher level of education and awareness among citizens of these parts of India.

hepatitis B virus (hepatitis B surface antigen ) was found to be the most prevalent transfusion transmitted infection among both replacement donations (1.39 %) and voluntary donations (0.47 %) which is comparable to other similar studies in India.<sup>10,15</sup> In contrast to our result, Singh et al. reported higher percentage (2.7 % in RD & 0.91 % in VD), however this study was limited by smaller sample size (850 donors).<sup>16</sup> Statistically significant (p = 0.0045) rising trend of hepatitis B surface antigen positivity (from 0.65 % to 1.06 %) was observed over a period of three years duration.<sup>17</sup>

hepatitis C virus infection is the second most common transfusion-transmitted infection in the present study, with prevalence of 0.49 % among replacement donors and 0.18 % among voluntary donors. Variable prevalence rates of hepatitis C virus infection has been reported in literature; 0.44 % among replacement donors and 0.18 % among voluntary donors,<sup>9</sup> 1.41 % among all blood donors and 1.62 % among replacement donors.<sup>16</sup> Seroprevalence rate of hepatitis C virus among the blood donor population in India is 0.53 to 5.1 %.<sup>18</sup> Wide variations of hepatitis C virus

seroprevalence reported by several studies from India might be due to variable sensitivity and specificity of different enzyme-linked immunoassay kits used for testing.<sup>10</sup>

Prevalence of human immunodeficiency virus was 0.14 % among replacement donors, while none of the donated units among voluntary donors were positive for human immunodeficiency virus. Higher human immunodeficiency virus seropositivity among replacement donors may be due to the fact that family may hide information related to the health condition due to pressure to save their patient's life.

Seropositivity of syphilis and malaria among replacement donors (RDs) was observed to be 0.43 % and 0.09 % respectively. None of donated unit among voluntary donors was positive for above diseases. Similar seropositivity of syphilis was also reported by Khamankar et al. (0.44 %),<sup>19</sup> while few other studies reported very low seropositivity.<sup>12,17</sup> Majority of studies from various parts of India reported zero seropositivity of malarial parasite.<sup>9,10,16</sup> Overall prevalence of transfusion-transmitted infection was 2.29 % with higher prevalence among replacement donors. Hiding the information regarding health conditions by Professional donors and replacement donors is the major cause of high infection rate among replacement donors.

## CONCLUSIONS

In developing countries, replacement donation is the major source of donation. Our study also showed a significantly higher number of replacement donations. Hepatitis B virus is found to be the commonest transfusion transmitted infection followed by hepatitis C virus and human immunodeficiency virus. None of the voluntary donated unit was positive for syphilis, human immunodeficiency virus and MP which shows better safety of blood and blood products obtained through voluntary donations. There should be more voluntary donations to achieve safer blood transfusion practices as self-deferral by donors with high risk condition is the most effective way to reduce prevalence of transfusion transmitted infections.

Strict implementation of donor selection criteria along with thorough history and examination is also very important to achieve safe blood transfusion in order to achieve low prevalence of transfusion transmitted infections. Screening with higher-generation sensitive enzyme-linked immunoassay kits and avoiding rapid screening methods can help to identify seropositive bags accurately. This may help to avoid transfusion of infectious whole blood and blood products, especially in patients requiring repeated transfusions as part of therapy. With the increasing use of nucleic acid amplification testing, developed countries have decreased the risk of transfusion transmitted infections to a major extent, but in the developing countries like India nucleic acid amplification technique is used by only few institutions due to the poor cost effectiveness. Apart from nucleic acid amplification testing, public awareness also plays important role to help in decreasing the infections. There should be more educational and motivational programmes to increase the voluntary donors and reduce the replacement donors towards minimum. For effective

implementation of voluntary donations, local potential blood donors should be motivated.

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