Original Article

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Seroprevalence and Trends of Transfusion Transmissible Infections among Blood Donors at A Tertiary Care Referral Teaching Hospital in Southern India

Transfusion Medicine Section

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ABSTRACT

Introduction: Blood transfusion is a life-saving measure in emergencies and is important for the medical treatment of every patient. Among all adverse effects of transfusion, transfusion transmitted infections (TTI) are very important. Accurate estimations on risk of TTI are needed, in order to monitor the safety of the blood supply.

Aim: The objective of the present study is to analyze the seroreactivity for TTI of apparently healthy blood donors.

Study Design: It is a retrospective cross sectional analytical study carried out in the Department of Transfusion Medicine at Sri Venkateswara Institute of Medical Sciences (SVIMS), Tirupati; Andhra Pradesh State, a tertiary care teaching hospital from January 2009 to December 2014.

Materials and Methods: The study was conducted on 41,942 blood donors. All blood donors were screened for hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV) by using the appropriate enzyme-linked immunosorbent assay and reactive donors were retested using a standard immunochromatographic technique. Malarial antigen testing was carried by rapid diagnostic device, which was based on immunochromatographic technique. The rapid plasma reagin (RPR) test was used for estimation of syphilis infection.

Results: A total of 41,942 blood donors were screened during the study period, of which 40,718 (97.1%) were males and 1,224 (2.9%) were females. The overall seroprevalence of TTI were 3.5% among these HIV, HBV and HCV were 0.7%, 2.3% and 0.4% respectively; for malaria and syphilis, the seroprevalence was estimated to be 0.02% and 0.05% respectively.

Conclusion: The risk of TTI remains despite of serological testing because of donors window period. Steps should be under taken to prevent these transmissions by careful selection of potential blood donors through a health history questionnaire and create opportunities for self-deferral.

Keywords: Donor screening, Malaria, Syphilis, Viral infections

INTRODUCTION

Among all adverse effects of transfusion, transfusion transmitted infections (TTI) are very significant. These include human immunodeficiency virus (HIV), Hepatitis B virus (HBV), Hepatitis C virus (HCV), Malaria parasite (MP) and Syphilis. Transmission of HIV can occur due to transfusion of whole blood or components including packed red cells, frozen plasma, cryoprecipitate and platelets derived from the blood of infected individuals. Other blood products like coagulation factor concentrates can also transmit HIV [1]. The risk of HIV transmission through infected blood products exceeds that of any other exposures. The first documented HIV infection in India was among a cohort of sex workers in the Southern part of Tamil Nadu, in 1986 [2]. The virus since then has been spreading rapidly across the country. India harbours the third largest number of HIV infected individuals in the world [3].

The prevalence of Hepatitis B is high in sub-Saharan Africa and east Asia, accounting for about 5–10% of the adult population. An estimated 2–5% of the general population is chronically infected in Middle East and in Indian subcontinent [4]. Globally it is estimated that 130-150 million people have chronic hepatitis C infection. A significant number of those who are chronically infected will develop liver cirrhosis or liver cancer [5].

Transfusion transmitted malaria can be a significant problem in malaria endemic countries because of the malarial parasite which is able to survive in blood stored at 4°C for days or weeks, and semi-immune donors with low level of parasitemia remain asymptomatic and can qualify as blood donors [6]. The prevalence of malaria is scantly reported ranging from 0% to 28% in some studies [7, 8].

The World Health Organization (WHO) estimated that there are 12 million new cases of syphilis each year, with more than 90% occurring in developing nations [9]. Moreover, in the past

30 years, through its association with an increased risk of HIV infection, serologic screening for syphilis has been justified in part as a surrogate marker [10].

Hence, this study was undertaken to analyze the seroreactivity for TTI of apparently healthy blood donors and the possible risk of these transmission through blood and blood components.

MATERIALS AND METHODS

This is a retrospective study carried out during the period January 2009 - December 2014 in the Department of Transfusion Medicine at Sri Venkateswara Institute of Medical Sciences (SVIMS), Tirupati; Andhra Pradesh State, a tertiary care teaching hospital in India. Written consent was obtained from all the donors and ethical clearance was obtained from the Institutional Ethical Committee. Blood donors, fulfilling the criteria for donor selection as per the selection criteria laid down by Drugs and Cosmetics Act, 1940 and Rules, 1945 were considered for the present study [11]. A total of 41,942 blood donors were screened during the study period. The donors were either voluntary or replacement donors. Voluntary donors in the blood banks or at voluntary blood donation camps were considered, while the replacement donors were either relatives or friends of patients. Data retrieved includes the demographic characteristics of donors such as age, sex, residence and the results of HIV, HBV, HCV, Syphilis and MP serologies.

Sample Collection and Laboratory Testing

Five milliliter of whole blood samples in Acid citrate dextrose (ACD) and 5 ml of whole blood samples were collected from the subjects into plain sterile tubes. ACD sample was used for MP testing and plain samples were centrifuged and the sera were separated and analyzed for different TTI; HIV, HBV, HCV, Syphilis as per the standard operating procedures followed in the blood bank. Samples were analyzed for antibodies to HIV1, 2 and p24 antigen (Microlisa HIV Ag & Ab, J.Mitra & Co. Pvt. Ltd, New Delhi, India), HBsAg (Hepalisa, J.Mitra & Co. Pvt. Ltd, New Delhi, India), and HCV (Microlisa HIV Ag & Ab, J.Mitra & Co. Pvt. Ltd, New Delhi, India), by ELISA. Any serum found reactive by the first assay was retested using a second assay based on different antigen preparations and/or different test principle using the anti-HIV test (HIV TRI-DOT, J.Mitra & Co. Pvt. Ltd, New Delhi, India), HBsAg (Hepacard, Diagnostic Enterprises, Parwanoo, India) and HCV by the anti- HCV test (HCV TRI-DOT, Diagnostic Enterprises, Parwanoo, India) which are immunochromatographic sandwich assays. Test for syphilis was done by RPR (RPR TEST, Span Diagnostics Ltd, Gujarat, India). Malarial antigen test was done by rapid diagnostic device, which is a pan malaria test based on detection of malaria parasite-specific lactate dehydrogenase (pLDH) (PAN MALARIA CARD, J.Mitra & Co. Pvt. Ltd, New Delhi, India) as per the manufacturer's instructions. The validity of the test was assured as per the given criterion and the results were computed.

RESULTS

A total of 41,942 donors were screened over a period of 5 years from January 2009 to December 2014, of which 40,718 (97.1%) were males and 1,224 (2.9%) were females. Among 41,942 donors, 25,993 (62%) were voluntary and 15,949 (38%) were replacement donors [Table/Fig-1]. The donors' age ranged from 18-60 years. Of all donors screened, 1,466 (3.5%) were reactive for different TTI. The prevalence of seroreactivity was more in the younger group than in the older age group constituting 52.6% (21-30 years), which was about 0.8% in donors of 51-60 years [Table/Fig-2]. There was no significant difference of TTI between the age groups (p=0.220). Out of 40,718 male donors 3.5% were reactive for different TTI and of 1,224 female donors, 2.7% were reactive for TTI [Table/Fig-3]. There was no significant difference between these two groups (p=0.500). Comparing the TTI prevalence between voluntary and replacement donors, 3.1% and 4.1% were reactive respectively [Table/Fig-4]. There was no significant difference between these (p=0.500). Out of all 1,466 reactive blood donors, HBV infections prevalence observed was 2.3% followed by HIV 0.7%, HCV 0.4%, MP 0.02% and 0.05% for syphilis [Table/Fig-5]. In the present study, decreasing trend for all the markers was observed during study period and it

Year	Total donations	Voluntary (%)	Replacement (%)	Male (%)	Female (%)
2009	5581	1087 (19.5)	4494 (80.5)	5423 (97.2)	158 (2.8)
2010	5452	1803 (33.1)	3649 (66.9)	5279 (96.8)	173 (3.2)
2011	5505	4196 (76.2)	1309 (23.8)	5283 (96.0)	222 (4.0)
2012	6952	4926 (70.9)	2026 (29.1)	6757 (97.2)	195 (2.8)
2013	8494	6269 (73.8)	2225 (26.2)	8302 (97.7)	192 (2.3)
2104	9958	7712 (77.4)	2246 (22.6)	9674 (97.1)	284 (2.9)
Total	41942	25993 (62)	15949 (38)	40718 (97.1)	1224 (2.9)

[Table/Fig-1]: Trends in voluntary and replacement donors and gender distribution during the study period

Age groups	HIV (%)	HBV (%)	HCV (%)	MP (%)	RPR (%)	Total (%)
<20	31 (19.6%)	101 (63.9)	23 (14.6)	0 (0)	3 (1.9)	158 (10.8)
21-30	168 (21.8)	512 (66.3)	76 (9.8)	7 (0.9)	9 (1.2)	772 (52.6)
31-40	53 (13.2)	285 (70.7)	55 (13.6)	2 (0.5)	8 (2)	403 (27.5)
41-50	22 (18.2)	76 (62.8)	19 (15.7)	1 (0.8)	3 (2.5)	121 (8.3)
51-60	2 (16.7)	9 (75)	1 (8.3)	0 (0)	0 (0)	12 (0.8)
Total	276	983	174	10	23	1466(100)

[Table/Fig-2]: Age-wise seroprevalence of TTIs among blood donors
p value=0.220: HIV- Human immunodeficiency virus, HBV- Hepatitis B virus, HCV- Hepatitis C virus, MP- Malaria parasite, RPR- Rapid plasma reagin

Blood donors	Total no	HIV	HBV	HCV	MP	RPR	Total (%)
Male	40718	265	966	169	10	23	1433 (3.5)
Female	1224	11	17	5	0	0	33 (2.7)
Total	41942	276	983	174	10	23	1466 (3.5)

[Table/Fig-3]: Seroprevalence of transfusion transmissible infections among blood donors (Gender-wise)
p=0.500: HIV- human immunodeficiency virus, HBV- hepatitis B virus, HCV- hepatitis C virus, MP- malaria parasite, RPR- rapid plasma reagin

Blood donors	Total No.	HIV	HBV	HCV	MP	RPR	Total (%)
Voluntary	25993	141	549	105	8	14	817 (3.1)
Replacement	15949	135	434	69	2	9	649 (4.1)
Total	41942	276	983	174	10	23	1466 (3.5)

[Table/Fig-4]: Seroprevalence of transfusion transmissible infections among blood donors (voluntary vs replacement)
p=0.500: HIV- Human immunodeficiency virus, HBV- Hepatitis B virus, HCV- hepatitis C virus, MP- Malaria parasite, RPR- Rapid plasma reagin

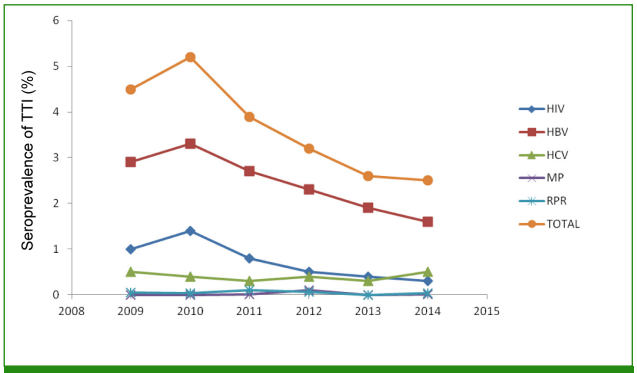
Year	No. of donors	HIV (%)	HBV (%)	HCV (%)	MP (%)	RPR (%)	Total (%)
2009	5581	55 (1.0)	166 (2.9)	29 (0.5)	0	3 (0.05)	253 (4.5)
2010	5452	77 (1.4)	179 (3.3)	23 (0.4)	0	2 (0.04)	281 (5.2)
2011	5505	43 (0.8)	151 (2.7)	18 (0.3)	1 (0.01)	6 (0.1)	218 (3.9)
2012	6952	32 (0.5)	163 (2.3)	29 (0.4)	8 (0.1)	5 (0.07)	237 (3.2)
2013	8494	34 (0.4)	161 (1.9)	24 (0.3)	0	0	220 (2.6)
2014	9958	33 (0.3)	163 (1.6)	50 (0.5)	1 (0.01)	4 (0.04)	251 (2.5)
Total	41942	276 (0.7)	983 (2.3)	174 (0.4)	10 (0.02)	23 (0.05)	1466 (3.5)

[Table/Fig-5]: Prevalence and trends of TTI among blood donors during 2009-2014
p=0.224: HIV- Human immunodeficiency virus, HBV- Hepatitis B virus, HCV- Hepatitis C virus, MP- Malaria parasite, RPR- Rapid plasma reagin

was declined from 4.5% to 2.5% from year 2009-2014. But it was not statistically significant (p=0.224) [Table/Fig-5,6].

DISCUSSION

In developing nations like India, blood safety continues to be a major problem due to the high prevalence of infectious markers among blood donors compounded with the problem of limited resources that preclude the use of sophisticated, sensitive but expensive technologies for screening of blood products [12]. The prevalence of TTI varies from country to country depending on the particular population from where blood units are collected.



[Table/Fig-6]: Trends of TTI prevalence during 2009-2014

In the present study, 3.5% of TTI prevalence was observed which was similar to the study done by Chaudhary et al., (3.4%) [13]. But it was so high compared to other studies by Chavan SK et al., [14] (1.96%) and Agrawal VK et al., (2.5%) [15]. In this study, voluntary donors were predominant constituting for about 62%, which was so small compared to the study done by Saghir et al., [16] (96%). A gradual increasing trend in voluntary donor population from 19.5% in 2009 to 77.4% in 2014 was observed in the present study [Table/Fig-1]. The abrupt rise after 2009 was due to broadened definition of voluntary blood donors by national AIDS control organization (NACO) [17], which included family replacement donors. Majority of the donor population in this study were males constituting 97.1% [Table/Fig-1] and this finding is similar to other studies conducted in India by Koram SK et al., [18] and Pahuja et al., [19]. TTI seroreactivity rate was more in 1,433 male donors (3.5%) than in 33 females (2.7%) [Table/Fig-3]. But it was not statistically significant (p=0.500). Similar findings were recorded in the study by Chaudhary K. et al., [13]. This might be attributed to more exposure of males to risk factors for TTI than females. Studies [19,20] have showed high seropositivity rate in RD compared to VD. In this study, it was observed that 3.1% of voluntary donors and 4.1% replacement donors had seroreactivity to TTI. No significant difference between these two (p=0.500) was observed. With respect to the age, TTIs were more prevalent in the age group of 21-30 years. Analyzing the individuals TTIs, it was observed that the prevalence of HBV was high in the 51-60 years (75%) age group, HCV in the 41- 50 years (15.7%) age group, syphilis in the 41 and 50 years (2.5%) age group and HIV in the 21-30 years (21.8%) age group. The difference of the prevalence of transfusion transmitted diseases among different age groups was statistically not significant (p=0.220). This is in contrast to the study done in Maharashtra [21]. They observed the prevalence of HBV in <20 years (100%), HCV in 31- 40 years age group (43.90%), syphilis in 41 - 50 years age group (16.66%) and HIV in 21-30 years age group (6.34%).

In this study the prevalence of HIV was observed in blood donors (0.7%). There was a gradual decreasing trend in HIV from 1% to 0.3% from 2009 to 2014 respectively [Table/Fig-5, 6]. The study of Patel SV et al., [22] observed the overall prevalence of HIV seropositivity among blood donors (0.3%).

This rate is also higher (0.06%) than that found in a study done in Mangalore by Fernandes H et al., [23].

The overall prevalence rate of HBsAg seroreactivity was 2.3% as observed in this study. The HBsAg seroreactivity was decreased from 2.9% in the year 2009 to 1.6% in 2014 [Table/Fig-5,6]. The study of Sinha SK et al., [24] observed the prevalence rate of about 2.27%. Higher prevalence of HBsAg is observed in general may be due to high prevalence of HBV infection in that population and hence the same was observed in the blood donors. Non repetition of the initial seroreactive samples may be one cause, as that can exclude false positive reactivity in those individuals.

The prevalence of Anti-HCV reactivity was 0.4%, which was more or less similar to the studies done by Das BK GB et al., [25] 0.35% and Makroo et al., 0.39% [26], higher than another study by Fernandes H et al., [23] in which it was 0.06%. In this study the researchers did not observe much variation in the prevalence of anti HCV seroreactivity during 2009-2014 [Table/Fig-5,6]. The reported variation in the prevalence of anti-HCV antibodies among blood donors in different regions of the world may be attributed to the differences in type, literacy rate and level of awareness among the blood donors. Use of lower sensitivity kits or technical errors may contribute to lower prevalence.

The prevalence of malaria in the present study was 0.02%, and was fairly correlating well with the study done by Dubey et al., [6] from Lucknow (0.01%). High prevalence of malaria had been observed in Nigeria by Agboola et al., (28%) [8], which may be due to high endemicity of that area. In India, some of the centers observed nil prevalence of malaria [27,28], which may be due to better screening of their donors before blood collection. In this study, the trend for malaria seropositivity was not changed much as it was fluctuating between 0 and 0.01%. The seropositive cases were observed mainly during rainy season, where the malarial vectors were breeding. In non endemic countries, donor deferral can be effective, but in endemic countries the problem is far greater as the majority of donors were potentially infected. As there is no appropriate test which can be done easily in screening blood donor for malaria, it has been suggested that anti- malarial drugs may be given to the recipients of blood in highly endemic areas.

Serological test for syphilis is done because the disease is characterized as being sexually transmitted and puts the donor at high risk for possible exposure to hepatitis and HIV, and justified in part as a surrogate marker [10]. The seroprevalence of syphilis in this study was 0.05% (ranging from 0.05% in 2009 to 0.04% in 2014). There was again a considerable variation in the prevalence rates of syphilis reported from different studies which may be due to differences in risk behaviour patterns. A study by Agarwal VK et al., from Dehradun, Uttar Pradesh [15] showed more or less similar prevalence (0.07%) compared to the present study while a study in Maharastra [6] showed lesser prevalence than in the present study (0.01%). In addition, the studies in Rajasthan [29] and Pakistan [30] showed a higher prevalence (0.51%, 0.43%) than in this study.

CONCLUSION

The risk of TTI remains despite of serological test because of donors' window period, viral varients, immuno silent or delayed seroconverting carriers and laboratory errors. Necessary precautions should be undertaken to prevent transmission through transfusion such as a careful selection of potential blood donors through a health history questionnaire and create opportunities for self-deferral. Programmes to prevent TTI infected donors should be aimed primarily at reducing high risk behaviors. It is hoped that the continued education of public about the methods of transfusion and increased availability of TTI testing will further reduce the seroreactivity and spread of the diseases. If a case of TTI is suspected, clinicians should report the case to the blood bank personnel. The public health surveillance system may perhaps collaborate with blood centers and health departments to conduct an investigation and look back into various other procedures.

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