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Transfusion Transmissible Infections among Blood Donors at the Blood Bank of Medical College of Gwalior: A 5 Year Study

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Authors' contributions

This work was carried out in collaboration between all authors. Author DCS designed the study, wrote the protocol, and wrote the first draft of the manuscript. Authors SR and SB managed the literature searches, analysis of the study performed and the spectroscopy analysis. Authors SI and SG managed the experimental process. Authors SS and BJ supervised the research work. All authors read and approved the final manuscript.

Original Research Article

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ABSTRACT

Introduction: Transfusion Transmitted Infections (TTIs) are a major problem associated with blood transfusion. Accurate estimates of risk of TTIs are essential for monitoring the safety of blood supply and evaluating the efficacy of currently employed screening procedures.
Aims: To determine the prevalence of transfusion transmitted infections among blood donors in greater Gwalior region and its surrounding areas i.e. central India and its comparison with other relevant studies.
Place and Duration of Study: Study was carried out at Blood Bank, Department of Pathology, Gajra Raja Medical College, Gwalior, India from January 2009 to December 2013 (5 year study).
Methodology: Total 67,123 blood units collected from blood donors were tested for transfusion transmitted infections (TTIs) i.e. HIV I & II, HBV, HCV,VDRL and Malaria parasite at Blood Bank as per guidelines of World Health Organization (WHO) for Asia Pacific region and Food and Drug Administration, Government of India.

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Results: Out of 67,123 blood units studied, voluntary units were 61309(91.3%) and replacement units were 5823 (8.7%). In the present study total TTIs positive units were 2747 (4.09%) (p=0.000005). Amongst them HBV were 2360 (3.51%) (p=0.000005), HIV positive units were 91(0.13%), HCV were 161 (0.24%), VDRL were 114 (0.17%) and Malaria 21 (0.03%).
Conclusion: Our study concluded that amongst all the TTIs in the blood donors in Gwalior and its surrounding area, seroprevalence of HBV was significantly higher than other infections. It is also higher than similar studies conducted in other parts of India.

Keywords: Transfusion transmitted infections; hepatitis B virus; human immunodeficiency virus; hepatitis C virus; blood donors.

1. INTRODUCTION

A well-organized Blood Transfusion Service (BTS) is an important component of the health care delivery system of any country. An integrated strategy for blood safety is required for elimination of transfusion transmissible infections (TTIs) and for provision of safe and adequate Blood Transfusion Services (BTSs) to the people. The main component of an integrated strategy includes collection of blood only from voluntary, non-remunerated blood donors, screening for all TTIs and reduction of unnecessary transfusion [1]. According to the National AIDS Control Organization (NACO) guidelines all blood samples must be tested for Human Immunodeficiency Virus (HIV) 1 and 2, Hepatitis B Virus (HBV), Hepatitis C virus (HCV), syphilis and malaria. All positive blood samples and blood units should be discarded [2].

An unsafe blood transfusion is very costly both from human and economic point of view. Morbidity and mortality resulting from the transfusion of infected blood have far reaching consequences, not only for the recipients themselves but also for their families, their communities and the wider society [3,4].

The economic cost of the failure to control the transmission of infection includes increase requirement for medical care, higher level of dependency, loss of productive labour force and placing heavy burden on already overstretched health and social services on national economy [3,5].

The higher prevalence of transfusion transmitted infectious diseases in India and other developing countries affect the blood safety for transfused recipients. Therefore, it should be mandatory that blood is screened for transfusion transmitted infectious diseases markers such as antibodies to HIV, surface antigen to HBV, antibodies to HCV, syphilis and malaria [6,7].

Hepatitis B is the most common disease of the world and has infected two billion people worldwide and has 400 million chronically infected cases [8]. It is also the 10^{th} leading cause of death worldwide, causing 500 000 to 1.2 million per year death due to chronic hepatitis, cirrhosis, hepatocellular carcinoma and other liver diseases [9,10]. In Asia and Africa, chronic HBV infection is common [11]. The Indian subcontinent is classified into intermediate HBV endemic (HbsAg carriage 2-7%) zone and has the second largest global area for chronic HBV infection [10], hence causing serious morbidity & financial burden and is thus a major global health problem [12]

There is wide variation of prevalence of blood borne infections among blood donors throughout the world; lack of study from central part of India i.e. in the population of Gwalior and its surrounding region of Madhya Pradesh propelled us to know the seroprevalence rate of infectious markers among blood donors and its comparison with other related studies in India and abroad.

2. MATERIALS AND METHODS

The study was conducted in Blood Bank, Department of Pathology, G. R. Medical College, Gwalior, India from 1st January 2009 to 31st December 2013 (5 years). Blood samples were collected from the blood donors who came to donate blood in Blood Bank/ or in voluntary blood donation camps. The majority of contributors to our blood bank are voluntary blood donors and rest is replacement donors. The voluntary blood donations were primarily obtained from blood donation camps mostly organized by clubs, colleges, political parties and religious organizations. Replacement donors are those who donated for ailing patients and were family members, close relatives or friends of the recipient. Blood donations from individuals suspicious for any of the TTI diseases were deferred. Moreover the donors were pre counseled and examined for their health status and also required to fill out a donor screening registration form as a part of a routine blood donation screening procedure. Informed consent was obtained from all the donors. The study abided by the rules of the ethical committee of G. R. Medical College, Gwalior.

Blood was collected from satellite bag in 3 ml plain sterile vial and 2 ml in ethylene diamine tetra acetic acid (EDTA) vial. All five tests i.e. HIV 1 and 2, HCV, HbsAg, VDRL and Malaria were performed in our Blood Bank, G. R. Medical College, Gwalior on collected samples and all tests are mandatory for each and every donor/or blood units. For the test procedures, we have a separate air conditioned laboratory equipped with all the necessaries like ELISA reader, ELISA washer, Incubator, multichannel and variable micropipettes etc as per guidelines of Food and Drug Administration, Government of India. Test kits and rapid cards were used as follows:

1. HIV antibodies detection: Microlisa HIV for HIV 1 & 2 (J. Mitra & Co. Pvt. Ltd.)
2. HCV antibodies detection: Microlisa 3rd generation (J. Mitra & Co. Pvt. Ltd.)
3. HbsAg antigen detection: Elisa Kit (J. Mitra & Co. Pvt. Ltd.)
4. HIV rapid card: HIV BI-DOT (J. Mitra & Co. Pvt. Ltd.)
5. HCV rapid card: HCV BI-DOT (J. Mitra & Co. Pvt. Ltd.)
6. HbsAg rapid card; HEPACARD (J. Mitra & Co. Pvt. Ltd.)
7. Syphilis : Rapid Plasma Reagin (RPR) for syphilis (Span diagnostics)
8. Malaria: Card method (PAN Malaria card by J. Mitra) one step rapid immune chromatographic test for P. Falciparum & P. Vivax.

All tests were performed according to manufactures instructions. The tests results were reported and the seropositivity rate of HBV, HCV, HIV, Syphilis and Malaria were calculated. All the reactive samples were repeated in duplicate before labeling them seropositive. As a Protocol, serovigilance of all the test results was performed by State Reference Laboratory (SRL), Department of Microbiology, G. R. Medical College, Gwalior and National Reference Laboratory (NRL), National Institute of Immunhematology, KEM Hospital, Mumbai. The blood unit was discarded as per guidelines of NACO whenever the pilot donor samples were found positive for any TTI.

3. RESULTS

In the present study a total of 67,132 blood units were collected at the blood bank from January 2009 to December 2013 (five years) in which voluntary blood donors were 61309 (90.3%) and rest 5823 (9.7%) were replacement donors (Table 1). Age of the donors ranged between 18 to 60 years. Male to female ratio in the study was; 64472 male (94%) and 2660 female (6%) (Fig. 1).

Table 1. Yearly distribution of Voluntary versus Replacement Donors

Year	Total blood donors	Voluntary blood donors	Replacement blood donors[o]
2009	12914	11788(91.3%)	1126(8.7%)
2010	12638	11449(90.6%)	1189(9.4%
2011	13106	11886(90.7%)	1220(9.3%)
2012	14001	12573(89.8%)	1428(10.2%)
2013	14473	13613(94.0%)	860(6.0%)
Total (5 Years)	67132	61309(91.3%)	5823(8.7%)

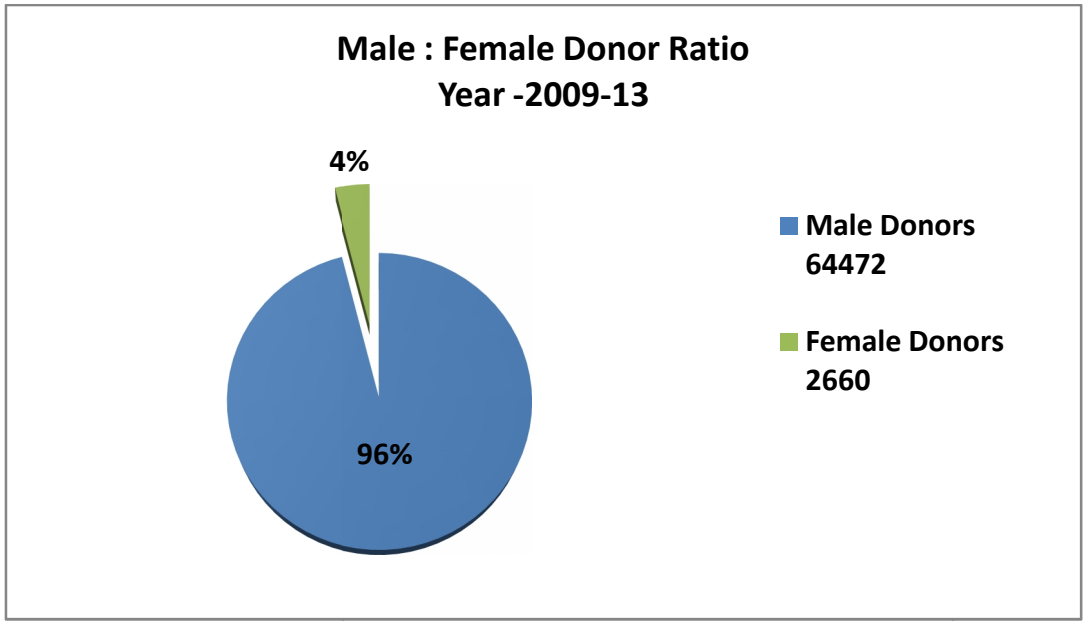

Fig. 1. Gender Ratio of Blood Donors

In year 2009 total number of donations were 12,914, in 2010 it was 13,106, in 2011, 2012, 2013 it was 13,106, 14,001 and 14,473 respectively (Table 1). Out of 67,132 blood donors, 2747 (4.09%) (p=0.000005) were tested reactive for TTIs. Out of these, seropositivity of HbsAg was 3.51% (2360 donors) (p=0.000005), HCV was 0.24% (161 donors), VDRL was 0.17% (114 donors) HIV was 0.13% (91 donors), while Malaria was 0.03% (21 donors) (Table 2). No donor has seropositivity for more than one infection in the study. The concurrent rates for seropositivity was highest for HbsAg followed by HCV, VDRL, HIV and Malaria in descending order.

Table 2. Seroprevalence of transfusion transmitted infections

Year	Blood donors tested	HIV reactive	HbsAg reactive	HCV reactive	VDRL reactive	MP positive	TTI positive
2009	12914	20(0.15%)	514(3.98%)	47(0.36%)	12(0.09%)	7(0.05%)	600(4.64%)
2010	12638	16(0.12%)	488(3.86%)	46(0.36%)	18(0.14%)	3(0.02%)	571(4.51%)
2011	13106	17(0.12%)	441(3.36%)	20(0.15%)	28(0.21%)	3(0.02%)	509(3.88%)
2012	14001	25(0.17%)	476(3.39%)	22(0.15%)	25(0.17%)	4(0.02%)	552(3.94%)
2013	14473	13(0.09%)	441(3.04%)	26(0.17%)	31(0.21%)	4(0.02%)	515(3.55%)
Total (5 Years)	67132	91(0.13%)	2360(3.51%)	161(0.24%)	114(0.17%)	21(0.03%)	2747(4.09%)

The trends in the seroprevalence of TTIs and HbsAg over a period of five years are shown in Fig. 1 while for HCV, syphilis and malaria are shown in Fig. 2. Overall seropositivity of TTIs has decreased from 4.64 to 3.55%. Prevalence of HIV, HbsAg and malaria has decreased from 0.15 to 0.09%, 3.98 to 3.04% and 0.05 to 0.02% respectively but VDRL reactivity has shown increasing trend from 0.09 to 0.21%.

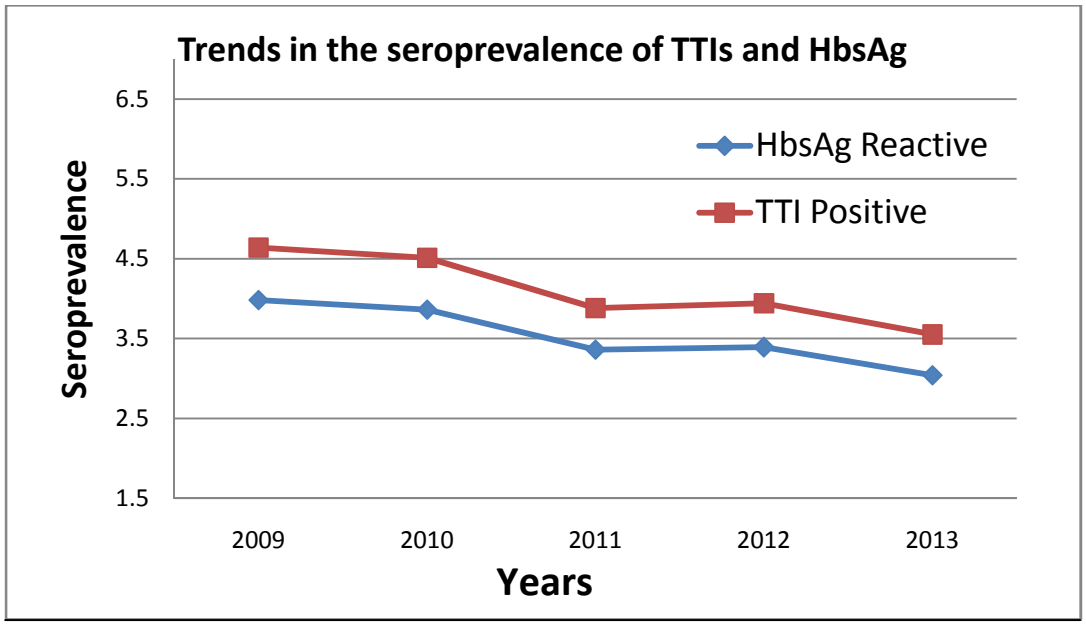

Fig. 2. Trends in seroprevalence of TTIs and HbsAg

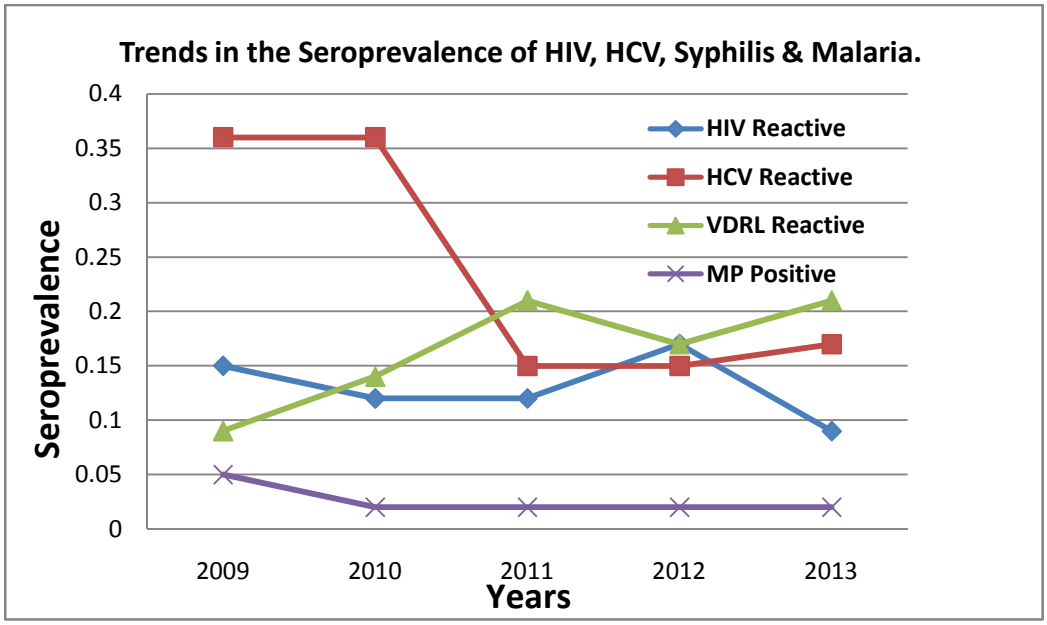

Fig. 3. Trends in seroprevalence of HIV, HCV, Syphilis and Malaria

4. DISCUSSION

Transfusion of blood and blood components is a life saving measure and help the people worldwide. At the same time however blood transfusion is an important mode of transmission of infections to the recipient. In developing countries the prevalence of TTIs is much higher and quite far from attending a zero risk level at the present moment [13].

This study showed that 2747 units (4.09%) of donated blood had serological evidence of multiple infections; most frequently HbsAg 2360 (3.51%), and HCV 161 (0.24%) followed by Syphilis 114 (0.17%), HIV 91(0.13%) and Malaria 21(0.03%). The prevalence of TTIs among Indian blood donors are reported to be ranging as follows; HBV-0.66% to 12%, HCV-0.5 to 1.5%, HIV 0.08% to 3.87% and Syphilis 0.85% to 3.0% [14,15]. The data providing a picture of TTIs burden from the different parts of India has also come from various seroprevalence studies (Table 3). In the present study, HBV and HCV were more common in donor population as compared to syphilis, HIV and malaria. Results of this study when compared with the studies conducted in 1999 and 2006 at Muhimbili National Hospital in Dar Es Salaam, Tanzania, by Matee M I et al. [16] and Mecky IN Matee et al. [17], they found higher prevalence of HIV, HBsAg, HCV and syphilis as 8.7%, 11.0%, 8%, 12.7% and 3.8%, 8.8%, 1.5%, 4.7% respectively while in the developed country, theoretical calculated residual risk for HIV, HCV and HBV is 1: 1.9 million donations (95% CI: 0.97–4.0 mill.), 1: 2.2 million donations (95% CI:1.2–4.6 mill.) and 1:115 000 donations (95% CI:69 900–206 000), respectively [8].

Table 3. Comparison of transfusion transmitted infections: prevalence rate in different parts of India

Place	Donors tested	HIV reactive	HbsAg reactive	HCV reactive	VDRL reactive	MP positive	Reference
Mangalore	9599	6(0.06%)	33(0.34%)	6(0.06%)	11(0.11%)	1(0.01%)	[13]
Dehradun	6751	9(0.13%)	67(0.99%)	13(0.19%)	42(0.62%)	0(0.00)	[14]
Ahmednagar	5661	4(0.07%)	62(1.09%)	42(0.74%)	4(0.07%)	--	[15]
Bhopal	5008	26(0.51%)	149(2.97%)	29(0.57%)	12(0.23%)	--	[20]
Lucknow	39060	170(0.44%)	497(1.27%)	90(0.23%)	111(0.28%)	--	[26]
New Delhi	28966	163(0.56%)	646(2.23%)	192(0.66%)	--	--	[27]
Ludhiyana	44064	37(0.08%)	290(0.66%)	483(1.09%)	373(0.85%)	--	[37]
Gwalior (present study)	67132	91(0.13%)	2360(3.51%)	161(0.24%)	114(0.17%)	21(0.03%)	--

No notable variation in seroprevalence of TTIs between voluntary / replacement and male/ female donors was observed. Higher frequency of voluntary blood donors (90.3%) in the study is a healthy sign for the transfusion services of India. Low frequency of female donors in the study were because of the fact that a large population of the females in India are usually underweight and anemic according to the donor's selection criteria and it is also due to traditional thinking of Indian society.

The seroprevalence of HBV by Purushottam A. Giri et al. [15] was 1.09% from Loni, Ahmednagar, Maharashtra and almost similar findings were noted by Chattoraj A et al. [14], Kaur et al [18] and Singh B et al. [19] while Hilda et al. [13] reported a low prevalence of 0.34%. Wide range of HBV seropositivity is also reported from different parts of India which ranges from 1.86 to 4% [20-24]. In our study seroprevalence of HBV was quite high (3.51%) as compared to studies done in other parts of India (Table 3 above). This may be because screening was done by two methods i.e. card and Elisa method followed by strict serovigilance monitoring and in rural areas use of common syringes are still prevailing for the medical treatment.

The diagnosis of HBV infection is based on the presence of HbsAg in the blood stream [25]. Our study raises serious concerns regarding safety of blood supply in our country as transfusion associated HBV is estimated approximately 50% or more in multi transfused patients and approximately 1.5% in post surgical patients [12]. India is still in the intermediate prevalence zone for the HbsAg and has been estimated to be a home for over 40 million HbsAg carriers [26]. Despite of the fact that safe and effective vaccine has been available since 1982; the HbsAg prevalence in India is still high. This is because of the fact that hepatitis B vaccination is not a part of our National Immunization Programme in India [27]. Prevalence is very high in Africa (13.4%) [28] as compared to Indian studies.

In our study 161 (0.24%) of blood donors were positive for HCV antibodies which is far less than studies conducted in Nigeria [29-31] while developed countries like USA and Europe reported between 0% and 1.4 % [32,33]. From Maharashtra, India [17] it was reported 0.74% and similar results were reported in other studies 0.78% [18], 0.79% [16], 0.88% [34]. As transmission of HCV is through blood exposure and in majority cases progresses to chronic infections, chances of cirrhosis and hepatocellular carcinoma are more than HBV.

Low incidence of seropositivity for HIV was seen in our study 0.13% (91 cases) as compared to other studies 0.32% [35], 0.23%(2004) & 0.35%(2005) [36]. India is the second largest home for HIV/AIDS. National data also suggest higher incidence of HIV in Chennai, Maharashtra and South India. But in our study seropositivity of HIV has decreased from 0.15 to 0.09% over a period of five years. The incidence reported from Africa is higher (1.8%) [28]. Prevalence of HIV has been in decreasing pattern in the Indian population because of the awareness of life threatening disease.

In our study seropositivity for syphilis is 0.17%. In other Indian subcontinent studies it is seen to be 0.01% [24], 0.11% [11], 0.07% [17], 0.85% [37] and 1.2% [38].

Malaria positive cases were 21(0.03%) in our study. A study shows that a rate of transfusion transmitted malaria varies from less than 0.2 in non-endemic countries to 50 or more cases per million in endemic countries as discussed by Mollison et al. [39]. In other parts of India it is 0.09% [24] and 0.01% [13].

The Indian subcontinent is classified as an intermediate Hepatitis B virus endemic zone (HbsAg carriage 2-7%) and has the second largest global pool of chronic HBV infection [10]. India has a population of more than 1.2 billion with 5.7million (reduced to 2.5 million) HIV positive, 43 million HBV positive and 15 million HCV positive people [17]. Blood/blood component is a major source of HBV, HIV, HCV, Syphilis and many other diseases [40,41].

Availability of safe blood for transfusion is a must for the recipients and community as well and can be achieved by vigorous and cautious screening of donors / or donated blood with laboratory screening tests.

5. CONCLUSION

From the results it is concluded that HbsAg infection still continues to be a menace to the society because, the incidence of the disease is still very high in the general population. Seropositivity of HIV has a decreasing pattern in Indian population. Implementation of strict selection criteria of donors as per guidelines laid down for blood banks in gazette notification of Government of India should be followed strictly.

6. FUNDING

This research did not receive any specific grant from any funding agency in the public, commercial or nonprofit organizations.

CONSENT

The authors declare that written informed consent was obtained from the patients before being recruited for this research.

ETHICAL APPROVAL

All author(s) hereby declare that all procedure have been examined and approved by the appropriate ethics committee of Gajra Raja Medical College, Gwalior, India and research have therefore been performed in accordance with the ethical standards laid down in the 1964 declaration of Helsinki.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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