

Research Article

Prevalence and trends of transfusion transmitted infections among blood donors of blood bank attached to government hospital of South Gujarat, India

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ABSTRACT

Background: Though the blood transfusion is lifesaving, it is never risk free and carries potential risk for transfusion transmitted infections (TTIs). The objective of present study is to assess the prevalence and trend of TTIs among blood donors in the blood bank attached to tertiary level government hospital and its comparison with national data and other studies of different regions.

Methods: Retrospective cross-sectional study was done including healthy blood donor of 18-65 years from May 2011 to April 2016. TTIs testing were done with 3rd generation ELISA for HIV, HBV and HCV and HIV testing was also done with 4th generation ELISA from the year 2014 onwards. Syphilis screening was done either by RPR, TPHA strip test or ELISA and Malaria parasite was tested either by peripheral smear or rapid test.

Results: From 40971 donors in study, 550 (1.34%) donors were sero-reactive from which 400 (0.98%) donors were reactive for HBV, 67 (0.16%) were for syphilis, 40 (0.098%) were for HCV, 33 (0.081%) were reactive for HIV and 10 (0.024%) were malaria positive. During the study period four donors showed co infection for HIV and HBV. Most common age group to be sero reactive in the present study is 21-30 years of age (43.09% of total).

Conclusions: Prevalence of TTIs in the present study was lower as compare to other studies of the India. The reasons behind this finding may be better pre-donation counseling, better life style, higher proportion of voluntary blood donation (> 99%) and high pre-donation deferral rate (11.17%).

Keywords: Transfusion transmitted infections, ELISA, Blood transfusion, Blood donors

INTRODUCTION

In many medical and surgical diseases of human beings, blood transfusion is a life-saving intervention. However blood transfusion is also having potential risk for Transfusion Transmitted Infections (TTIs). The risk for acquiring TTIs is even higher in multiple transfused patients. The study conducted by Mittal et al stated that 12.5% multiple transfused patients were infected with TTIs.¹ Screening of blood donors first started in 1947.² To prevent spread of TTIs through blood transfusion, Government of India has made mandatory to screen

donated blood for HBV (since 1971), HIV (since 1989) and HCV (since 2001).³⁻⁵ However risks of TTIs is still persist due to blood donation by infective donors during the window period. According to study conducted by Schreiber GB et al, among donors whose units passed all screening tests, the risks of giving blood during an infectious window period were estimated as follows: for HIV, 1 in 4, 93,000; for HCV, 1 in 1, 03,000; and for HBV, 1 in 63,000.⁶

National adult (15-49 years) HIV prevalence is estimated at 0.26% (0.22%-0.32%) in 2015 (0.30% among males

and 0.22% among females).⁷ With 3.7% point prevalence, that is, over 40 million HBV carriers, India is considered to have an intermediate level of HBV endemicity. The population prevalence of HCV infection in India is 1%.⁸ Considering the lack of regional data for prevalence of these diseases, the present study analysis and its comparison were done with national data and other studies of different regions. Evaluation of data for the prevalence of TTIs permits an assessment of acquisition of these infections in blood donor population and it also gives information about epidemiology of infections in population.

METHODS

This was a retrospective cross sectional study carried out in blood bank of tertiary level government hospital of South Gujarat, India involving healthy blood donors between the age group of 18 to 65years. The study includes total 40,971 units collected over a period of five years from May 2011 to April 2016 and the record was analyzed. All blood donors who were included in this study, satisfied the criteria for blood donation as per Drugs and Cosmetic Act 1940 (and rules there under) supplemented by the Technical Manual 2003 (Directorate General of Health Services, Ministry of Health and Family Welfare, Govt. of India). All information regarding blood donors like demographic data, weight, hemoglobin status and result of serological test was recorded and maintained by the blood bank.

Blood was screened for HIV, HBV, HCV, syphilis and malaria. The TTIs testing were done with 3rd generation ELISA for HIV, HBV and HCV on pilot tubes samples as

well as samples from the bag in case of reactive test results. The additional test for HIV was 4th generation ELISA from the year 2014 onwards. Test for Syphilis was either of three – RPR, TPHA strip test or ELISA and the test for Malaria was either peripheral smear or rapid test.

All tests were performed as per manufacturer instructions and standard operative procedures of TTI lab of the blood bank maintaining quality control like use of in-house low positive external controls and participation of the TTI lab in third party international level External Quality Assessment Schemes. The prevalence of TTIs over the five years was calculated and record of all donors who tested reactive for any of the TTIs was also examined.

The statistical analysis was done using Epi infoTM version 7.1.4.0 by applying Extended Mantel-Haenszel chi square test for linear trend.

RESULTS

Total of 40971 apparently healthy adult donors were screened for TTIs during the study period. Out of 40971 blood donors 39807 (97.16%) were males and 1164 (2.84%) were females. The overall prevalence of TTIs markers reactive donors over the five years is shown in Figure 1. From 40971 donors in study, 550 (1.34%) donors were sero-reactive from which 400 (0.98%) donors were reactive for HBV, 67 (0.16%) were for syphilis, 40 (0.098%) were for HCV, 33 (0.081%) were reactive for HIV and 10 (0.024%) were malaria positive. During the study period four donors showed co infection for HIV and HBV.

Table 1: Age wise distribution of sero-reactivity among blood donors.

Year	18-20	21-30	31-40	41-50	51-60	≥61
2011	4	26	11	2	2	0
2012	9	45	26	22	5	0
2013	3	42	46	11	4	0
2014	15	63	37	23	5	1
2015	7	42	37	14	6	0
2016	1	19	17	4	1	0
Total	39	237	174	76	23	1

Table 1 shows age wise distribution of TTIs. Most common age group to be sero reactive in the present study was 21-30 years of age (43.09% of total), followed by 31-40 years (31.64%) and least common age group was >50 years. Gender wise distribution showed that out of 550 TTIs marker sero reactive donors, only nine female donors was found to be sero reactive (1.6% of total reactive donors) but this finding was statistically insignificant considering lower numbers of total female

donors (p value >0.05, Extended Mantel-Haenszel chi square test).

Trend over five years showed that HIV prevalence declined statistically significant from 0.2 % in 2012 to 0.09% in 2016 (p value <0.05, Extended Mantel-Haenszel chi square test for linear trend). HBV prevalence progressively declined from 1.04 % in 2011 to 0.98 % in 2016. Prevalence of HCV was around 0.08% in years

from 2011 to 2014, while in 2015 prevalence was 0.15 % and in 2016, prevalence was about 0.1 %.

Highest prevalence of Syphilis was seen in the year 2013 (0.31%), after that trend was declining and in the year 2015 it was 0.02%. Trend of malaria over five years was from 0% to 0.07% (Figure 2). There were variations in overall sero reactivity of TTIs as well as individual marker trends, but except for HIV, the variations of prevalence rates were statistically insignificant (p value >0.05 , Extended Mantel-Haenszel chi square test for linear trend).

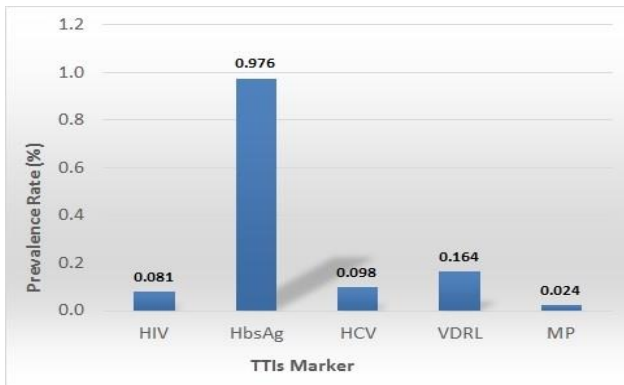


Figure 1: Overall prevalence of TTIs markers.

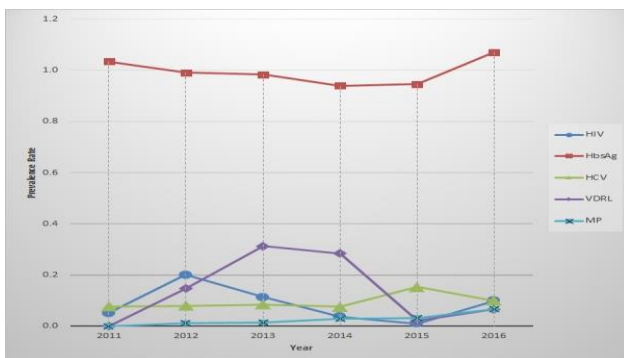


Figure 2: Trends of TTIs during study period.

DISCUSSION

Though the blood transfusion plays a vital role in management of many diseases, it always carries a risk of TTIs and many other adverse reactions. Blood transfusion is a highly avoidable treatment ever prescribed. There is no screening method to reduce the risk of TTIs to zero; it appears that it is essential to adopt strict criteria in the selection of donors and to avoid unnecessary transfusion.⁹

During the study period, the rate of all five mandatory TTIs markers was 1.34%. The other studies in India by Agarwal N et al and Leena M S et al (0.87% and 1.35% respectively) also found similar to lower TTIs marker rates while studies done by Amrutha Kumari B et al, Kotwal U et al and Kumar R et al (2.81%, 3.02% and 4.57% respectively) concluded for higher rates.¹⁰⁻¹⁴ The

reason behind lower rate of TTIs markers in present study might be because of greater than 99% of blood collection was from voluntary donors and pre donation deferral rate was 11.17%. There was statistically insignificant increase or decrease in overall trend in sero reactivity for TTIs markers in the present study ($p>0.05$) which is in contrast to the finding of the study done by Leena MS et al (0.04 in 2004-0.4 in 2010) and Makroo RN et al (0.52 in 1992-0.72 in 1993) in which significant increase in the trend of sero reactivity of blood donors.^{11,15} Kurl A et al (1993-2003) in Ludhiana, reported declining trend of sero-markers.¹⁶ In present study, the prevalence was found for individual TTIs markers in decreasing order as follows: HBV, Syphilis, HCV, HIV and Malaria were respectively 0.98 %, 0.16 %, 0.098%, 0.081 % and 0.024 %.

The prevalence of HBV is higher in male and female both in the present study. Among all TTIs markers, highest prevalence was for HBV (0.98 %) in present study, but its prevalence was less as compared to 1.77 %, 1.13 % and 1.03 % which were found in studies done in Karnataka, Orissa and Punjab respectively.^{12,14,17} Various studies reported that sero-prevalence of HBV among blood donors was higher than HIV, HCV and syphilis.^{16, 18-20} A low prevalence of HBV of 0.71 % and 0.62 % were reported in studies in South India and at costal Karnataka.^{11,21}

According to the National Center for Disease Control, the population prevalence of HCV infection in India is 1%.⁸ The sero reactivity rate for HCV in blood donors in present study was nearly one tenth (0.098 %) of the prevalence rate of HCV infection in population. As shown in table 2, majorities of blood donors studies from different regions of India has higher prevalence rate as compare to present study.^{11,12,14,17-19} However during the last two years of present study, the prevalence rate has increased to about 0.154 % and 0.100, which were in correlation with study findings of Leena MS et al and Amrutha Kumari B et al.^{11,12}

Syphilis screening of donated blood has been considered to have value as a 'lifestyle' indicator, as individuals exposed to syphilis may also have been exposed to other sexually transmitted diseases and, therefore, should not donate.²² Thus it serves primarily as a surrogate test to identify donors with potentially high risk behavior. Our study shows prevalence of Syphilis was 0.16%, which is similar to the prevalence rate of the studies done by Leena MS et al while other studies of Table 2 has shown higher prevalence.^{11,12,14,18}

The HIV/AIDS pandemic has focused particular attention on the importance of preventing TTIs. Up to 3% of HIV infections worldwide are transmitted through the transfusion of contaminated blood and blood products.²³ As per HIV estimation report by NACO in 2015, national adult HIV prevalence was 0.26%.⁷ In present study, five year prevalence rate was 0.081% with highest numbers of

HIV reactive donors were in 2012. HIV prevalence at our center declined from 0.20% in 2012 to 0.1% in 2016. The reasons for this is not clear but may be increased awareness in blood donors for HIV and self-rejection related to it, improved pre-donation counseling of voluntary blood donors, deferring the donors with high

risk behavior, successful post donation counseling of sero reactive donors and increased voluntary blood donors in comparison of replacement donors. Compared to other studies mentioned in table 2, prevalence rate in present study was low.^{11,12,14,17-19}

Table 2: Prevalence rate of TTIs markers in different studies of India.

Studies	Study region	Study Period	TTIs markers prevalence rate				
			HBV	HCV	HIV	Syphilis	Malaria
Leena MS et al ¹¹	South India	2004-2010	0.71	0.14	0.27	0.1	0.129
Amrutha Kumari B et al ¹²	Karnataka	2006-2010	1.77	0.13	0.63	0.28	
Kumar R et al ¹⁴	Punjab	2008-2013	1.03	1.53	0.26	1.74	0.006
Panda M et al ¹⁷	Orissa	2005	1.13	1.98	0.35		
Srikrishna A et al ¹⁸	Bengaluru	1997-1998	1.86	1.02	0.44	1.6	
Sastry JM et al ¹⁹	Pune	2008-2013	1.23	0.41	0.28	0.008	0
Singh K et al ²¹	Karnataka	2005-2007	0.62				
Present Study	South Gujarat	2011-2015	0.98	0.098	0.081	0.16	0.024

The fifth and mandatory but neglected marker for TTIs screening in India is Malaria. Malaria is endemic in the study region and its positivity rate in general population was 15.01% during the year 2012 as concluded in the study done in this region by Kevadiya SM et al.²⁴ The five year prevalence rate for malaria was 0.02% with highest prevalence rate of 0.06% in the year 2016 in the present study. This lower prevalence rate of malaria in blood donors was because of better pre donation screening and good knowledge of malaria related symptoms in blood donors. Two other studies from India had reported malaria rate of 0.129% (Leena MS et al in South India) and 0.006% (Kumar R et al in Punjab).^{11,14}

Most blood banks in India use ELISA kit, which cannot detect HIV before 22 days, HBV before 59 days and HCV before 82 days of infection. As large volumes of blood or blood components are given to patients during transfusion therapy, even a blood unit with a low viral load may cause infection in the recipient. It is imperative that blood transfusion services have effective screening systems to detect, segregate and remove reactive blood donations and all components derived from these donations from the quarantined useable stock. Only non-reactive blood and blood components should be released for clinical or manufacturing use. The majorities of the problems are due to the prevalence of asymptomatic carriers in the society, as well as blood donations during the window period of infections also poses a great threat to safe blood supply.

Replacement donors carry relatively higher risk of transfusion transmitted infections due to chances of missing professional donors during donor screening procedures. Hence blood from replacement donors should be accepted only in cases of dire emergencies when

transfusion of blood or blood products would be lifesaving. The present study has limitation of use of ELISA test for TTIs screening. The latest more sensitive methods such as PCR and NAT can uncover latent infections in the window period and may actually suggest underestimation of prevalence by currently used screening tests in the present study. This implies that screening for TTIs needs to be upgraded across blood banks in India.

CONCLUSION

Prevalence of TTIs in the present study was lower as compare to other studies of the India. The reasons behind this finding may be better health status of the blood donors as compare to general population, better life style, higher proportion of voluntary blood donation (>99%), high pre donation deferral rate (11.17%) and effective impact of government programs of Integrated Counseling and Testing Centers and ART centers. HBV was the most prevalent TTI among all, so there is need of initiating efforts for community level health program for HBV in addition to UIP with HBV vaccine started in 2007 and the government should focus present youth population which has not taken this vaccine in childhood life.

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