Prevalence and Risk Factors of Transfusion-Transmitted Infections among Blood Donors in a South Indian Tertiary Care Setting

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Abstract

Blood transfusion is an important mode of transmission of infections to recipients. Evaluating trends in the prevalence of transfusion transmissible infections among blood donors is essential for monitoring blood supply safety and donor screening effectiveness. This study aimed to assess the seroprevalence of transfusion-transmissible infections among blood donors in the blood bank of a tertiary care teaching hospital in Bangalore, India. All consenting blood donors were consecutively included from Jan 2012 to Dec 2015 and were screened for seroprevalence of HIV, HBV, HCV and syphilis. A total of 4087 donors were tested, out of which 2681(65.6%) were replacement donors, 1406 (34.5%) were voluntary donors and 93% were males, 6.5% were females. The overall seropositivity rates of HIV, HBV, HCV & Syphilis were respectively 0.2%, 0.75%, 0.34% & 0.3% respectively. None of them were positive for malarial parasite. Seropositivity was more among males than in females and in replacement donors when compared to voluntary donors. Thus there is the need for non-remunerated voluntary donor services to be instituted. Also further prevalence rates of HCV and Syphilis to be studied in this region as there is greater fluctuation among them so that necessary steps are taken to provide safe blood to the recipients.

Introduction

The discovery of transfusion-transmissible infections (TTIs) has heralded a new era in blood transfusion practice worldwide with emphasis on two fundamental objectives, safety and protection of human life. Although blood transfusion plays an important role in the supportive care of medical and surgical patients, unsafe transfusion practices also put millions of people at risk of transfusiontransmissible infections. With every unit of blood, there is 1% chance of transfusion-associated problems including transfusion transmitted diseases (Fiebig, 2008; Chandra *et al*., 2009).

According to WHO, safe blood is a universal right. To improve blood transfusion safety, it recommends an integrated strategy including establishment of well-organized blood transfusion services, prioritization of blood donation from voluntary nonremunerated donors, screening of donated blood for at least the four major TTIs such as HIV, Hepatitis B, Hepatitis C and Syphilis with quality-assured assays, rational use of blood and implementation of effective quality control systems (WHO, 2002).

Selection of blood donors with low TTI risk and effective laboratory screening has reduced the risk of transmission to very low levels in the past 20 years (Stokx J *et al*., 2011). This has become especially important in developing countries where 80% of population has access to only 20% of safe blood unlike in developed countries where 20% of

population has access to 80% of safe blood as per WHO global database on blood safety (www.searo. who.int/en/section10/section17/section58/section 225. htm). This may be due to the effectiveness of the system of educating and selecting Donors.

India has a population of more than 1.2 billion with 5.7 (reduced to 2.5) million Human

Immunodeficiency Virus (HIV) positive, 43 million Hepatitis B Virus (HBV) positive and 15 million Hepatitis C Virus (HCV) positive persons. The risk of transfusion transmission of these viruses may be alarming due to high seroprevalence of HIV, anti-HCV, and HBs Ag (0.5%, 0.4%, and 1.4%, respectively) among blood donors (Nancy Singh, 2011). The four possible risks for these TTI's include the immunological window period (the period during which serological tests are negative in an infected donor); asymptomatic chronic carriers whose serology tests are negative; atypical infections or mutant strains and technical errors in the laboratory (Bedoya JA, 2012).

Poor health education and lack of awareness result in the reservoir of infections in the population. Only continuous improvement and implementation of donor selection, sensitive screening tests, and effective inactivation procedures can ensure the elimination or reduction of the risk of acquiring TTI's.

Apart from HIV no regular serosurveillance for hepatitis B and C and syphilis are usually conducted in the adult general population in India. As there was no large scale study on seroprevalence of

hepatitis B and C at regular interval, seroprevalence among blood donors can be used to monitor the

trend of these TTIs in the apparently healthy adult population in community. (Karmakar PR *et al.,* 2014).

Also it is essential to know the prevalence rates of TTI's, especially in the Indian setup where voluntary donations are fewer and poorly structured and safety of blood could still be compromised since these infectious agents persist in the circulation of asymptomatic individuals who are healthy enough to be blood donors. The aim of the present study is to evaluate the data for the prevalence of TTI's in our hospital transfusion service setup which permits assessment of acquisition of these infections in the blood donor population & consequently the safety of the collected blood donations.

Monitoring the trends gives an idea of epidemiology and disease burden of these infections in the community and accurate measurement of risk versus benefits of blood transfusion. This also helps in implementing strategies for prevention of these infections so as to ensure safe blood to the recipients.

Material and methods

Study design

The present study was cross sectional study carried out at the blood bank of a tertiary care teaching hospital in Bangalore, India. All the voluntary and replacement donors attending blood bank from January 2012 to December 2015 were included in the study.

Ethical and institutional issues

The study has been approved by institutional ethics committee. Informed consent of the participants were collected while blood donation. Prior permission from Chief Medical Superintendent as well as blood bank medical officer was also obtained.

Data collection procedure

We have a well-established blood bank with regular FDA inspections and internal audits. The data of donors, quality control registers, TTI

registers, issue registers are well maintained. Confidentiality of personal data is maintained. Donors were screened by trained personnel after a complete physical examination and satisfactorily answering the donor's questionnaire as per WHO guidelines/Govt. of India.

Inclusion criteria–Haemoglobin more than12gm/dl for both sex, weight more than 50kg, Exclusion criteria - Age less than 18 and more than 60yrs, history of medication, recent jaundice, previous surgery, lactation and menstruation females. Care was taken to eliminate professional and paid donors by taking history and clinical examination.

Donor registration forms, which included a detailed pre-donation questionnaire, were filled by the donors. Information regarding age, sex, risk factors

like history of surgery, chronic illness, hospitalization, blood transfusion, occupation, high risk behavior, tattoo marks, history of vaccination or any episode of jaundice was recorded.

Definitions/terms used in the study Voluntary donors - Donated blood without any incentive for the cause. Replacement donors- Donated blood in exchange for receiving blood

units for their patients.

Processing of collected blood unit: From these units, samples were collected in test tubes at the time of bleeding and were screened for TTI's viz. Hepatitis B Virus, Hepatitis C Virus, Human Immunodeficiency Virus, Syphilis and malaria.

Details of serological tests: Tests were performed according to the manufacturer's instructions.

- Hepatitis B surface antigen (HBs Ag) was tested by Microlisa ELISA (J. Mitra and Co. Pvt. Ltd.) which is enzyme immunoassay technique for detection of surface antigen of HBV
- Anti HCV antibodies were tested by thirdgeneration HCV Microlisa ELISA (J. Mitra and Co. Pvt. Ltd.) for detection of HCV
- Human immunodeficiency virus (HIV-1 & HIV-2) was tested by Microlisa ELISA (J. Mitra and Co. Pvt. Ltd.)
- Syphilis was tested by RPR-Rapid Plasma Reagin Kit (modified slide test, SPAN Diagnostic) and
- Malaria was screened by SD Malaria Kit (one step, rapid immunochromatographic test)

Simultaneous In house positive and negative controls were performed for each reagent lot. All the reactive samples were repeated in duplicate as recommended by NACO. Repeat reactive were labelled as seropositive for respective infection and were discarded.

Results

A total of 4087 blood donors were screened during a period of 4years (Jan 2012 to Dec 2015) at blood bank of our hospital. of the total donors, 1406 (34.5%) were voluntary, 2681(65.6%) were replacement donors and 93.5% were males,

6.5% were females as shown in Table 1 & 3.

The overall seropositivity rates of HIV, HBV, HCV & Syphilis were 0.2%, 0.75%, 0.34% & 0.3% respectively which is depicted in Fig.1. None of them were positive. for malarial parasite. Table 2 shows the comparison of seroprevalence in donor category. eropositivity was more among males (1.6%) than females (0.75%) which is shown in Table 3. Trends of seroprevalence of TTIs over 4 years are depicted in Fig. 2. Which shows greater fluctuations in prevalence rates of HCV and Syphilis than HIV and HBV. blood are very few due to lack of awareness, motivation, education regarding blood donation

and also many of the Indian women face disqualification while being screened for blood donation since there is a very high incidence of anemia especially in the child bearing age.

In our study replacement donors were more in number than voluntary donors similar to various studies (Arora D *et al*., 2010; Yedlapati B *et al*., 2010; Huggi V *et al*., 2014).

Unlike few other studies where voluntary donors were more than replacement donors (Fernandes H *et al*., 2010; Kulkarni N, 2012; Khamankar ST *et al*., 2014) and this probably reflects the deficiency of proper health education programmes.

Globally HIV is one of the biggest challenges faced by the health services. According to WHO, orldwide the estimated adult prevalence of HIV is around 0.8% in general population by the end of 2015. In India, according to the latest estimates the National adult HIV prevalence is 0.26% in general population and in blood donors 0.28% (Annual Report NACO 2015-2016). In the various studies, the seroprevalence of HIV among blood donors varies from 0.04% to 0.92%. In our study it was 0.17% in total donors. The declining trend of HIV seropositivity may be due to the effect of preventive programmes that have been instituted in recent years by the government. India, being a medium endemic area, faces a challenge with Hepatitis B, one of the most infectious diseases.

It is a major source of transfusion hepatitis and is associated with carrier state and chronic liver disease. Up to 40 million of 350 million hepatitis B chronic carriers worldwide are in India (Datta S, 2008). HBs Ag prevalence varies from 1-13%, with an average of 4.7% (Deepti Sachan, 2013).

The seroprevalence of HBV in our study was 0.75% which is lower compared to other studies (Arora D *et al*., 2010; Yedlapati B *et al*., 2010; Das B K *et al*., 2011; Purushottam A *et al*., 2012, Sharma D.C *et al*., 2014; Arshad A *et al*., 2016). Fernandes H *et al* & Gauravi *et al* have reported lower rates of 0.34% & 0.68%. The frequency of

The need of the hour is to shift the burden to voluntary blood donations and this has been emphasized by various authorities and researchers through a multidisciplinary approach by various government agencies. The overall seroprevalence was 1.59% with a higher prevalence in replacement donors than voluntary donors. Seropositivity rates of HIV, HBV, HCV & Syphilis were 0.2%, 0.75%, 0.34% & 0.3% respectively. Table 4 shows the comparison of seropositivity rates with various other studies across India and few neibhouring countries.

HBV is more than other TTI's may be because of presence of asymptomatic carrier state.

Table 4. Prevalence of TTI's in different parts of India and Neibhour

Place	HIV %	HBV
Arora D et.al., Haryana,2010	0.3	1.7
Yedlapati B *et al*., A.P, 2010	0.39	1.4
Fernandes H et.al., Mangalore, 2010	0.06	0.3
Das B K *et al*., Kolkata 2011	0.32	1.5
Kulkarni N *et al*., Bellary, 2012	0.9	3.2
Purushotam *et al*., aharashtra,2012	0.07	1.0
Sharma D C *et al*., Gwalior, 2014	0.29	1.1
Karmakar P R *et al*., Kolkata, 2014	0.6	1.4
Khamankar S *et al*., Wardha, 2014	0.92	3.2
Gauravi A *et al*., Rajkot, 2014	0.074	0.6
Huggi V *et al*, Bellary., 2014	0.17	2.6
Murtuza shaikh *et al*., Maharashtra, 2015	0.51	2.2
Arshad A *et al*., Pakistan, 2016	0.04	1.8
Shreshta A *et al*., Nepal, 2009	0.12	0.4
S Yang *et al*., China, 2016	0.08	0.5
Present Study	0.2	0.7

HCV carriers in India are around 12-13 million (Narahari S, 2009). Seroprevalence of HCV in our study was 0.34%. It is relatively low compare to the other studies with the range of 0.35% - 1% (Arora D *et al*., 2010; Yedlapati B *et al*., 2010; Sharma D.C *et al*., 2014; Karmakar P R., 2014; Murtuza Shaikh *et al*., 2015). S Yang, 2016 has reported a lower rate of 0.2%. There is a wide variation in HCV Seroprevalence in different studies in India, the reason behind which may be the usage of different generations of ELISA test kit having different sensitivity and specificity.

Seroprevalence of Syphilis was 0.3% in the present study which is at a slightly of higher range compared to other studies (Yedlapati B *et*

al., 2010; Kulkarni, N 2012; Purushottam A *et al*., 2012; Sharma D.C *et al*., 2014; Huggi V *et al*., 2014) which can be reflection of changing lifestyle and more open social norms in the society. Arora D *et al*., 2010 and Arshad A *et al*., 2016 have reported a higher value of 0.9% and 2.1% respectively. The variable trends of TTI's in our study during this period of 4 years could be explained due to different lifestyles, awareness, donor selection criteria and sensitivity and specificity of test procedures. The possible limitations of our study are chances of missing occult HBV infection, HBV infection in the window period, in the convalescence phase and in chronic infection with very low level of viremia because the absence of Hbs Ag in blood donors may not be sufficient to ensure the lack of circulating HBV.

Conclusion

Although the overall rates of all the TTI's were comparable with other studies, it was noted that the seroprevalence rates for HCV and Syphilis fluctuated greatly while the seroprevalence of HIV and HBV were relatively consistent during the study period. The study thus concludes that proper surveillance of the prevalence rates of HCV & Syphilis to be done so that necessary steps are taken for ultimate goal of providing safe blood to recipients. Awareness among the public about the benefits of voluntary blood donations is to be increased. This can bring a change in the attitude of the people so that non-remunerated voluntary donor services can be instituted. Extensive strict donor selection and screening procedures can improve the blood safety.

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