Original Research Article

Seroprevalence of transfusion transmissible infections among blood donors in tertiary care centre of Gandhinagar, Gujarat, India

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Abstract

Background: Transfusion transmissible infections (TTI) is a major challenge to the blood transfusion service all over the world. TTI create a significant burden on health care system that continue to be a threat to safe transfusion practices. Safety of blood is a major concern in transfusion therapy. In spite of advancement of technologies and meticulous testing one cannot detect the infections in "Window Phase". **Aims and Objectives:** To study the sero-prevalence of TTIs among blood donors andto assess the trend of TTIsamong blood donors from records at the blood bank of our tertiary care hospital. **Materials and Methods:** The present study was carried out at Blood bank of GMERS Medical College, Gandhinagar, Gujarat, India and includes the analysis of seroprevalence of HIV, HBV, HCV, Syphilis and Malaria in the blood donors during the period of 3 years and 6 months from January 2015 to June 2018. **Results:** Out of total 13724 blood donors, replacement donors (52.4%) were more in comparison to voluntary donors (47.6%). The seropositivity among the blood donors in our study was 0.29% for HBV, 0.04% for syphilis, 0.03% for HIV and 0.0% for both HCV and malaria. The seroprevalence of HIV and syphilis showed a declining trend while seroprevalence for HBV was increasing trend over 3 years. **Conclusion:** Voluntary blood donation, increasing awareness about blood donation in general population, selection of repeat, non- remunerated, regular voluntary blood donors and diligent donor selection are most important to increase blood safety and avoid transmission of infectious disease through blood transfusion.

Key words: Transfusion Transmissible Infections, Blood Donors, Hepatitis, Human Immunodeficiency Virus, Syphilis.

Introduction

Blood transfusion has been used since 1930 for variousindication [1]. Screening of blood donors first started in 1947 [2]. TTI create a significant burden on health care system that continue to be a threat to safe transfusion practices of blood & components and one of the major problem in delayed transfusion hazards. Blood is a life saving resource; still it can be the one of the sources of infective diseases if there remain any lacunae in screening of blood during processing [3].

The magnitude of the TTI varies from country to country depending on the load of TTI in that particular population from where blood units are sourced [4]. Thus, ensuring the safety of blood is a major concern in transfusion therapy. This has necessitated formulation of a National Blood Policy and development of a National Blood Program under NACP. The policy aims to ensure easily accessible and adequate supply of safe and quality blood and blood components collected / procured from a voluntary non-remunerated regular blood donor in well-equipped premises, which is free from transfusion transmitted infections; is stored and transported under optimum conditions [5].

WHO recommends that all blood donations should be screened for infections prior to use. Screening for HIV, Hepatitis B, Hepatitis C, and syphilis should be mandatory. Blood screening should be performed according to the quality system requirements [6]. In India, testing of blood units for human immuno-deficiency virus (HIV I and II), Hepatitis B virus (HBV), Hepatitis C virus (HCV), syphilis and malaria is mandatory [7].

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In spite of meticulous testing one cannot detect the infections in "Window Phase". In spite of technological advancements, the problems of 'window period', false-negative results, prevalence of asymptomatic carriers, genetic variability in viral strains and technical errors to be considered [8].

As per global estimates a total of 33.3 million people are living with HIV. The prevalence of HIV in India is 0.3% among the general population [9]. Prevalence of HIV among blood donors was noted to have a wide range between 0.02% and 8.5% in various studies. Punjab is classified as a low prevalence states per NACO (National AIDS Control Organisation) [10].

According to the World Health Organisation (WHO), HBsAg (Hepatitis B surface antigen) prevalence among the general population ranges from 0.1% to 11.7%. HBV prevalence in the general population in India is 2-8% and1-2% in the blood donors, according to various studies. Approximately 3% of the world population is infected with Hepatitis C virus (HCV).

Aims and Objectives

To study the seroprevalence of TTIs among blood donors and to assess the trend of transfusion transmitted infections (TTIs) among blood donors from records at the blood bank of our tertiary care hospital.

Materials and Methods

Study Design: The present study was carried out at Blood bank of GMERS Medical College and General Hospital, Gandhinagar - a tertiary care hospital in Gandhinagar district of Gujarat state, India and includes the analysis of seroprevalence of HIV, HBV, HCV and Syphilis in the blood donors who donated their blood units at our blood bank during the period of 3 years and 6 months from January 2015 to June 2018.

All the voluntary as well as replacement blood donors were selected preferentially after detailed clinical history, proper counselling and thorough clinical examination. Informed consent of the participants were also collected while blood donation.

The screening of all blood units was done by Enzyme Linked Immuno Sorbent Assay (ELISA), for HIV I & II, Hbs Agand HCV. Erba Lisa Sen HBs Ag kit was used for detection of HBsAg. Erba Lisa HIV gen was used for detection of antibodies to HIV virus. Erba Lisa HCV gen (v2) kit was used for detection of antibodies to HCV virus, while Rapid Plasma Reagin test kit was used for syphilis. These kits were provided by National AIDS Control Organisation (NACO). The criteria for validity of tests and their cut off value for reporting positive results were retested for confirmation. All tests were done meticulously following the standard guidelines. The data regarding age, sex and serology report was collected from blood bank records.

It was analysed to evaluate the overall seroprevalence as well as distribution of seroprevalence according to age, sex of donors, type of infection and the trend over 3.5 years. Seropositive units were discarded as per biomedical discard management regulations.

Data collection procedure: We have a very well-established blood bank with component separation facility 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 than and equal to 12.5 gm/dl for both sex, weight more than 45 kg, Age between 18 to 65 years.

Exclusion criteria: Age less than 18 and more than 65 years, previous donation within 3 months, history of medication, recent jaundice, previous surgery, lactation and menstruation females. Care was taken to eliminate professional and paid donors by taking detailed 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 behaviour, tattoo marks, history of vaccination or any episode of jaundice was recorded.

Details of the kits used for screening of serological tests: All serological tests were performed according to the manufacturer's instructions.

Antibody to Human immunodeficiency virus (HIV-1 & HIV-2) was tested by ELISA method Merilisa HIV I & II (Meril Diagnostics Pvt. Ltd.). Hepatitis B surface antigen (HBs Ag) was tested by ELISA method Erbalisa SEN Hbs Ag (Transasia Biomedicals Co.) which is enzyme immunoassay technique for detection of surface antigen of HBV. Anti HCV antibodies were tested by ELISA method Erbalisa HCV third-generation

(Transasia Biomedicals Co.) for detection of HCV antibodies. Syphilis was tested syphilis antibody rapid test by trust line strip (Athenese Dx Pvt. Ltd.). 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 again retested by another method and if found reactive labelled as seropositive for respective infection and were discarded.

Results

Table-1: Donor category and Sex distribution.

Year	Voluntary Donors			Replacement Donors			Total
	Male	Female	Total	Male	Female	Total	
2015	1207	123	1330	1582	03	1585	2915
2016	1679	207	1886	2040	12	2052	3938
2017	1561	225	1786	2485	10	2495	4281
2018	1362	167	1529	1056	05	1061	2590
Total	**5809**	**722**	**6531**	**7163**	**30**	**7193**	**13724**

Table 1 shows that total 13724 blood donors had been screened for transfusion transmissible infections in our study during a period of January 2015 to June 2018 at blood bank of our hospital. Out of 13724 total donors, 6531 (47.6%) were voluntary, 7193 (52.4%) were replacement donors and 12972 (94.5%) were males and 752 (5.5%) were females. Among 6531 voluntary donors, 5809 (88.9%) were males and 722 (11.1%) were females. Among 7193 replacement donors, 7163 (99.5%) were males and 30 (0.5%) were females.

Table-2: Seroprevalence of TTI's in various donor categories.

TTI's	Voluntary	Replacement	Total
HIV I & II	01 (0.01)	03 (0.04)	04 (0.03)
HbsAg	18 (0.28)	22 (0.31)	40 (0.29)
HCV	00	00	00
Syphilis	00	05 (0.07)	05 (0.04)
Malaria	00	00	00
Total Reactive	19 (0.29)	30 (0.42)	49 (0.36)
Total Donors	**6531 (47.6)**	**7193 (52.4)**	**13724**

Table 2 shows seroprevalence of all TTI's in donor categories. With respect to individual TTIs, it was observed that out of total 13724 donors screened, the maximum 40 number of donors were found positive for HBV infection followed by 05donors positive for syphilis and 04 donors were positive for HIV. Thus the proportion (in percentages) of TTIs among blood donors at blood bank during five study period was the maximum for HBV (0.29%), Syphilis (0.04) and least for HIV (0.03%). Among total 40 HBV positive donors, 22 were replacement donors and 18 were voluntary donors. Among total 40 syphilis positive donors, 22 were replacement donors and 18 were voluntary donors.

Table-3: Year wise distribution of TTI in blood donors

TTI's	2015 (%)	2016 (%)	2017 (%)	2018 (%)	Total (%)
HIV I & II	02 (0.07)	00	01 (0.02)	01 (0.04)	04 (0.03)
HbsAg	08 (0.27)	09 (0.22)	17 (0.40)	06 (0.23)	40 (0.29)
HCV	00	00	00	00	00
Syphilis	04 (0.14)	01 (0.03)	00	00	05 (0.04)
Malaria	00	00	00	00	00
TotalReative	14 (0.48)	10 (0.25)	18 (0.42)	07 (0.27)	49 (0.36)
Total Donors	**2915**	**3938**	**4281**	**2590**	**13724**

Table 3 shows that out of total 13724 donors screened 49 donors were found seropositive for transfusion transmissible infections. So, prevalence rate was 0.36% (49/13724). Among all seropositive cases maximum cases 40 (0.29%) were of HBV infection, followed by 05 (0.04%) cases of Syphilis, 04 (0.03%) cases were of HIV, and 00 (0.0%) for HCV and MP antigen both. It also shows about year wise trend of individual TTIs, it was found that for HIV infection there was a

steady pattern throughout the study. There was a rising trend forHBV infection from 0.27% in 2015 to 0.40% in 2017 with a decline in percentage only in 2018. The pattern of trend of syphilis showsan upsurge of infection in donors in the year 2015 followed by a decline in 2016.

Table-4: Sex wise distribution of TTI in blood donors.

Sex	No. of Donors	HIV I & II	HbsAg	HCV	Syphilis	MP	Total
Male	12972	04	40	00	05	00	49
Female	752	00	00	00	00	00	00
Total	13724	04	40	00	05	00	49

Table 4 shows sex wise distribution of TTI results in blood donors. Out of total 12972 male donors, 49 (0.38%) were TTI positive. Out of total 752 female donors, nobody was positive for TTI.

Discussion

Blood being a scarce and expensive human resource, should be prescribed judiciously and appropriately. Prescribing decisions should be basedon national guidelines on the clinical usage of blood; taking the individual patient's needs into consideration, with minimum cost and wastage, optimum safety and efficacy [11]. TTI is a major challenge to the blood transfusion service all over the world. There is a long list of viruses, parasites, and bacteria, which can be transmitted through blood transfusion.

Among them, important transfusion transmissible infections are Human immunodeficiency virus (HIV-I/II), Hepatitis B virus (HBV), Hepatitis C virus (HCV), Syphilis and Malaria. Despite of pre-donation counselling and medical fitness test, the presence of TTIs is inevitable in blood donations. Majority of the problems are due to prevalence of asymptomatic carriers in the society, as well as blood donations during the window period of infections, transfusions can contribute to an ever-widening pool of infection in the population [12]. Only continuous improvement and implementation of donor selection, sensitive screening tests, and effective inactivation procedures can ensure the elimination, or at least reduction, ofthe risk of acquiring TTIs [13].

In our study, most prevalent age group was between 22 to 35 years. There were total 49 seropositive donors from this age group. Mandal et al also found the highest prevalence of TTI in the age group of 26-35 years [14]. The peaking of infection rates in adulthood suggests a close relationship of acquisition of infection in sexually active age groups and may include high risk behaviour population [15].

In our study, the seropositivity in females was nil than that in males. Yanase et al studied the prevalence of TTI among the Filipino blood donors and found that males were at increased risk of both HBV and HCV [16]. Makroo et al observed that the risk of being reactive was three times higher in male donors when compared with female donors [17]. Karmakar et al in their study from Kolkata, India, have also shown high seropositivity rates in male donors compared to female donors [18].

In the present study out of total 13724 donors, 6531 (47.6%) were voluntary donors and 7193 (52.4%) were replacement donors. Too high predominance of replacement donors was noted by Singh et al [19], Kakkar et al [20] and Pahuja et al [21] as 82.4%, 94.7% and 99.48% respectively in their study. While predominance of voluntary donors was noted by Bhattacharya et al [22] and Shah et al [23] in their study, which reflects presence of awareness about blood donation in general population and the importance of repeat, non- remunerated, regular voluntary donations.

Promotion of voluntary donations would further reduce the risk of both single as well as co-infections. Hence, the emphasis should be to maximize voluntary blood donations so as to minimize the risk of TTI in accordance with the National Blood Policy of India [7]. The present study revealed that TTI's were more prevalent in replacement donors than voluntary donors. Similar observations with high sero-positivity in replacement donors was observed by Singh et al [19] and Pahuja et al [21]. On the other hand Chandra et al [24] have found almost negligible infectivity rate in voluntary donors and also no voluntary donor was found to be positive for HIV by Arora Det al [25]. The difference in the values of seropositivity in different studies may be due to the difference in prevalence of TTI in different areas, the effectiveness in selection of donors and variable proportion of voluntary and replacement blood donations in different studies.

The sero-prevalence of TTIs in the present study was highest for HBV infection (0.29%). This finding was similar to study conducted by Chandra et al[24], Sawke et al [26] and Bhawani et al [27] who have also found

HBV to be the commonest TTI among the donors in different percentages being 1.96%, 2.90% and 1.41% respectively. The prevalence of syphilis infection in donors was next to HBV infection being 0.04% in the present study. The third highestprevalence of TTI in the present study was HIV being 0.03%. Other studies conducted in various parts of India reported HIV prevalence in donors as 0.23%, 0.51%, 0.39% and 0.08% [24,26,27,28]. For HIV, India is second only to South Africa in terms of overall number of people living with HIV [21]. A WHO report states that the viral dose in HIV transmission through blood is so large that one HIV positive transfusion leads to death, on an average, after 2 years in children and after three to 5 years in adults [24]. In our study, no any blood donor was found seropositive for HCV and malaria but other studies reported HCV prevalence as 0.34%, 0.57%, 0.84% and 1.09%[24,26,27,28].

Conclusion

Out of total 13724 blood donors, replacement donors (52.4%) were more, in comparison to voluntary donors (47.6%). Seropositivity of TTI were more prevalent in replacement donors than voluntary donors. The number of blood donors have increased from year 2015 - 2018, there was an increasing trend for both males and females but there was male preponderance in both voluntary and replacement donors.

The seropositivity among the blood donors in our study was 0.29% for HBV, 0.04% for syphilis, 0.03% for HIV and 0.0% for both HCV and malaria. There was no any donor with coinfection over the study period in our study. The prevalence was highest among the sexually active age group of 18-37 years. The seroprevalence of HIV and syphilis showed a declining trend while seroprevalence for HBV was increasing trend over 3 years. Voluntary blood donation, increasing awareness about blood donation in general population, selection of repeat, non- remunerated, regular voluntary blood donors and diligent donor selection are most important to increase blood safety and avoid transmission of infectious disease through blood transfusion. Replace-ment and voluntary donors should be screened thoroughly before blood donation and professional donors should be out rightly rejected. Public awareness and counselling could also help in curbing these infections and increase blood safety.

Take home message- We recommend that donors should be screened thoroughly before blood donation and professional donors should be out rightly rejected. We must increase awareness about blood donation in general population.

Author Contribution- First author Dr. Renu Sharma has prepared the study design and drafted manuscript in presentable manner for publication in journal. Second and corresponding author Dr. Kanaiyalal J Patel and fourth author Dr. Chetan Dharaiya has done all correspondence with editor. Third author Dr. Harshid Patel has collected all datas and done study in his own institute.

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