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Seropositivity of HBsAg and HCV among blood donors at the blood bank of a tertiary care teaching hospital in Central India

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Abstract

Background: *Safe blood transfusion is of utmost importance as an unsafe blood transfusion bears lot of burden on human life and economy. Transfusion-transmissible infectious agents such as human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV) and syphilis are among the greatest threats to blood safety for the recipient. To assess the magnitude and dynamics of disease transmission and for its prevention and control, the study of its seroprevalence is important. O The present study was carried out with an aim to assess the trend and seroprevalence of transfusion transmitted infections (TTIs) among blood donors at our blood bank.*

Materials & Methods: *All voluntary donors reporting to the blood bank were screened for HBsAg, Hepatitis C Virus (HCV), HIV and Syphilis by using the appropriate enzyme-linked immunosorbent assay. Hepatitis B Virus (HBV) was tested for surface antigen (HBsAg) and HCV by the immunechromatographic method. The study was designed for duration of one year between January 2017 to December 2017. Medical reports of the donors were accessed from the hospital records and analyzed.*

Results: *A total of 2471 blood donors were screened during a period of 1.5 years (January 2017 to Dec 2017) at blood bank of our hospital. Among them, 882 (35.7%) were voluntary and 1589 (64.3%) were replacement donors. The overall seroprevalence of HBV and HCV was 28 (1.13%) and 5 (0.20%) respectively. The percentage of HBs Ag seropositivity was 1.2% (25/2091) in males and 0.79% (3/380) in females. The highest prevalence of HBs Ag seropositive 15 /28 (53.57%) was within the age group 18-30 years, followed by 11 (39.29%) within the age group*

31-40 years. The percentage of anti-HCV seropositivity was 0.19% (4/2091) in males and 0.26% (1/380) in females.
Conclusion: *Voluntary blood donation and diligent donor selection are important to increase blood safety and avoid transmission of infectious diseases through blood transfusion. Strict measures in donor screening including better donor recruitment, promoting voluntary blood donation, screening of blood and blood products using high sensitivity serological assays, other infectious diseases markers would considerably improve the current screening procedure for blood donation and enhance the safety of the blood intended for transfusion.*
Keywords: *Hepatitis B Surface Antigen (HBs Ag), Anti-HCV, Seroprevalence, Transfusion transmitted infections, Blood donors.*

Introduction

Transfusion transmissible infections (TTI) create a significant burden on health care system. 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. Hepatitis B virus (HBV) and Hepatitis C virus (HCV) was among the first virus known to be transmitted by blood and blood products.[1]

India, as reported to be an endemic country for human immunodeficiency virus (HIV) infection and HBV infection, screening for these viruses poses a serious challenge for blood banking community. The most reliable method for preventing HBV transmission is screening the blood donors for the presence of major part protein of the virus, Hepatitis B surface antigen (HBsAg) in their serum.[2,3]

India has a population of more than 1.2 billion with 5.7 million Human Immunodeficiency Virus (HIV) positive, 43 million HBV positive and 15 million HCV positive persons. The risk of transfusion transmission of these viruses may be alarming due to high seroprevalence of HIV, HCV, and HBV (0.5%, 0.4%, and 1.4% respectively) among the blood donors.[4] Despite education and availability of drugs and vaccines it is estimated that 2 billion people have evidence of past or present infection with HBV worldwide and 248 million are chronic carriers of HBV surface antigen (HBsAg), particularly in low and middle-income countries (LMICs).[5] About 40 million chronic carriers of HBV arise in India itself.[6] Transfusion of infected blood is a key transmission route of HBV; other practices that confer risks for HBV infections include tattooing, piercing, acupuncture, multiple sex partners, surgeries and occupational and vertical transmission. Blood safety therefore remains an issue of major concern in transfusion medicine. Screening of blood donors for the presence of the Hepatitis B surface antigen (HBsAg) in their serum is an important method for preventing HBV transmission by blood transfusion.[2] In all settings, screening of blood donors for HBsAg should be mandatory with linkage to care, counselling and treatment for those who are test positive.[7]

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.[8] In India, testing of blood units for human immunodeficiency virus (HIV I and II), Hepatitis B virus (HBV), Hepatitis C virus (HCV), syphilis and malaria is mandatory.[9]

Hepatitis B is one of the common TTI. In most of the blood banks the diagnosis of HBV infection is based on the presence of Hepatitis B Surface Antigen in the Blood stream which does not confirm the absence of HBV infection. The occult HBV infection can only be diagnosed by HBc and HBV DNA. Many workers had shown a significant numbers of HBsAg negative blood donors were anti HBc positive and exposed to HBV infection. These donors are potential for transmitting HBV contaminated blood.[10] Hepatitis C virus (HCV) is another important cause of post transfusion non-A non B hepatitis and 200 million individuals had chronic HCV infection. The global seroprevalance of HCV among blood donors varies from 0.4-19.2%.[11]

The risk of transfusion transmission of these viruses may be alarming due to high seroprevalence of HIV, anti-HCV, and HBsAg (0.5%, 0.4%, and 1.4%, respectively) among

blood donors.[12] Safety assessment of the blood supply, the quality of screening procedures and the risk of transfusion transmitted infectious diseases (TTIs) in any country can be estimated by review and analysis of the records of blood donors for screening procedures and the prevalence of serological markers of infectious diseases.

Materials & Methods

A cross-sectional hospital study was conducted at the blood bank of a rural tertiary care teaching hospital in Dewas, Madhya Pradesh India. Data were collected for a period of one year between January 2017 to December 2017. The study has been approved by institutional ethics committee. Informed consent of the participants were collected while blood donation. All donors who donated blood at blood bank as well as at various blood donation camps organized by our blood bank were included in this study.

Sera of civilian residents from various localities and of different age groups, who donated blood voluntarily was screened for HIV, HBsAg, HCV, and syphilis. A total of 2741 blood units were collected and studied. The ethics committee of the institute approved the study. Exclusion criteria for blood donation were current history of medication, recent history of having undergone a surgical procedure, serious illness, previous blood transfusions, weight 60 years, pregnant and lactating women. Exclusion of donors for the blood donation was done as per NACO guidelines. The screening methods for the detection of TTIs at our blood bank is HIV – Tridot (immunoassay); HBV – HEPACARD (for HbsAg detection: Immunoassay based on sandwich principle); HCV – Tridot (immunoassay); VDRL– ASPEN Syphilis Rapid test (qualitative membrane based immunoassay); and Malaria – Satya 2.0 Pf/Pv Malaria Antigen (Card test). Data regarding sex of the donor, type of donors, and screening tests results were collected and tabulated in MS excel sheet. Statistical analysis of the collected data was carried out.

Definitions/terms used in the study Voluntary donors' means who donated blood without any incentive for the cause. Replacement donors' means who donated blood in exchange for receiving blood units for their patients. Donors were selected by taking history, clinical examination (strictly following donor's selection criteria) to eliminate professional donors and including donors who gave voluntary written consent for screening of their blood for TTIs. A detailed pre-donation questionnaire was included in donor registration form. Information regarding risk factors like history of surgery, previous illness, hospitalization, blood transfusion, occupation, high risk behaviour and tattoo marks was collected. All the reactive samples were repeat tested before labelling them seropositive and respective blood units were discarded as per standard protocols. 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. Seropositive units were discarded as per bio discard management regulations.

Results

A total of 2471 blood donors were screened during a period of 1.5 years (January 2017 to Dec 2017) at blood bank of our hospital. Among them, 882 (35.7%) were voluntary and 1589 (64.3%) were replacement donors. In the present study 2091 (84.62%) were males and 380 (15.38%) were females which show predominance of males as compared to females for the studied 1 year [Table 1].

The prevalence of HBsAg and anti-HCV, among voluntary blood donors in the study population is showed in Table 1. The overall seroprevalence of HBV and HCV was 28 (1.13%) and 5 (0.20%) respectively. The higher prevalence was observed for HBV followed by HCV, in decreasing order. The initial screening test revealed that 36 (1.46%) were found to be initially seroreactive for HBsAg

in the first assay. When the reactive samples were further tested by the ELISA in duplicate, was 28 (1.13%) were found repeat reactive (seropositive as per WHO criteria) and 8 (0.32%) samples were negative. The percentage of HBs Ag seropositivity was 1.2% (25/2091) in males and 0.79% (3/380) in females. The highest prevalence of HBs Ag seropositive 15 /28 (53.57%) was within the age group 18-30 years, followed by 11 (39.29%) within the age group 31-40 years, followed by 2 (7.14%) was within the age group 41-50 years and with the lowest prevalence [0%] was observed within the age group of (51-60 years). There was not a single donor positive for syphilis. There was only single donor with co-infection of HIV and HCV. The percentage of anti-HCV seropositivity was 0.19% (4/2091) in males and 0.26% (1/380) in females. Most of the donations 1589 (64.3%) were replacement compared to 882 (35.7%) voluntary donation. Higher prevalence of TTIs was noted in replacement donors compared to voluntary donors.

Table 1: Profile of seropositive blood donors and prevalence of TTI's among males and females

Characteristics	Number of donors	Percentage
Voluntary donors	882	35.7%
Replacement donors	1589	64.3%
Males	2091	84.62%
Females	380	15.38%
Total donors	2471	100%
HBs Ag seropositive	28	1.13%
HBs Ag seropositivity in males	25/2091	1.2%
HBs Ag seropositivity in females	3/380	0.79%
Anti-HCV seropositivity in males	4/2091	0.19%
Anti-HCV seropositivity in females	1/380	0.26%

Discussion

The current study presents the prevalence of HBV and HCV infection in blood donors of a tertiary care referral teaching hospital in Dewas, Madhya Pradesh. 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 non-remunerated 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, 2010).[7]

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).[13] 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. This may be due to the effectiveness of the system of educating and selecting Donors.[7]

Blood transfusion is a potential route of transmission of these TTIs.[7] Screening of blood is now mandatory for many diseases and is undertaken routinely in blood banks. Transmission of TTIs during the serologically window period still poses a threat to blood safety in environments where there is high rate of TTIs. HBV and HCV are the two established causes of post transfusion hepatitis. The prevalence of TTIs among the Indian blood donors is reported to be ranging as follows; HBV – 0.66% to 12%, HCV – 0.5% to 1.5%, HIV– 0.084% to 3.87%, and syphilis – 0.85% to 3% respectively.[14]

In the present study, out of total donors, 882 (35.7%) were voluntary and 1589 (64.3%) were replacement donors. Similar predominance of replacement donors was noted in other studies [15-20] while on the contrary, Sunderan S et al[21], Bhattacharya P et al[10], Shah N et al[22] noted predominance of voluntary donors in their studies. In the present study, higher prevalence of TTIs was noted among replacement donors as compared to the voluntary donors, which is in concordance with the other studies [10, 22-25], where as only Kakkar N et al[19] reported marginally higher prevalence among voluntary donors.

Table 2: Seroprevalence of individual TTIs among different studies

Studies	HBV	HCV
Sunderam S et al[21]	1.01%	0.14%
Shaikh M et al[4]	2.21%	1.11%
Yadav BS et al[15]	1.77%	0.09%
Arora D et al[16]	1.7%	1.0%
Agrawal P et al[26]	0.84%	0
Pahuja S et al[17]	2.23%	0.66%
Shah N et al[22]	0.97%	0.10%
Mandal R et al[23]	1.24%	0.62%
Philip CJ et al[24]	1.7%	0.3%
Pallavi P et al[25]	1.27%	0.23%
Kaur H et al[27]	0.75%	1.79%
Fernandes H et al[28]	0.34%	0.06%
Sinha SK et al[29]	2.27%	
Rani K et al[30]	2.14%	
Mathai J et al[31]	3.1%	
Lavanya V et al[32]	3.5%	
Makroo et al[33]	0.29%	
Jain R et al[34]	1.37%	
Present study	1.13%	0.20%

The overall prevalence rate of HBsAg seroreactivity is 1.13% as observed in our study. This is slightly lower than to the observations of Sinha SK et al., (2012)[29] i.e. 2.27% and Rani K et al., (2011)[30] i.e. 2.14%. There is slight variation when compared to the prevalence rate reported by others like Mathai J et al.[31], 3.1%7 and Lavanya V et al.[32], (2012) 3.5%. Comparatively, a lower prevalence was observed by others, a prevalence of 0.29% reported by Makroo et al., (2008)[33] after a multicenter evaluation in blood donors by simultaneous serological and individual donor nucleicacid amplification (ID-NAT) testing; 0.34% by Fernandez H et al., (2010)[28], 1.37% by Jain R, Gupta G (2012)[34]. The prevalence of HBsAg either higher or lower observed may depend on actual prevalence of HBV infection in general population, repetition of the initial seroreactive samples and technical errors causing high or low absorbance value.

We observed the trends of HBsAg seroreactivity and it was found that it was variable but always in low prevalence zone (less than 2%) according to WHO statistics during the entire period.[7] Decline in HBsAg seroreactivity was found in the later years. Among population-based studies HBsAg prevalence among general population groups ranged from 0.1% to 11.7%, being between 2% to 8% in most studies, HBsAg prevalence rate among blood donors ranged from 1% to 4.7%[35], our study showed seroreactivity in low prevalence zone (1.13%.) . In comparison with the other parts of India also the present study shows low seroprevalence of hepatitis B infection (Table 2). The prevalence of HBsAg observed either higher or lower may depend on actual prevalence of HBV infection in general population, repetition of the initial seroreactive samples and technical errors causing high or low absorbance value. The present study revealed that HBV infection was more prevalent among replacement blood donors than voluntary donors (0.60% vs. 0.15%, respectively) as also noted in the study of Sonwane et al.[36]

The replacement donors were usually friends or relatives of the recipients. Sometimes replacement donors due to social factors may conceal their high risk activities to their relatives. In the study by Dhar G et al[37] it was observed the seroreactivity was higher in replacement donors (1.39%) than voluntary donors (1.09%) The concealment of Medical history and life style are the important causes of seropositivity among the voluntary and replacement donors. Higher seropositivity was observed in replacement donors in this study.

Study by Koshy JM et al[38] showed that seropositivity among the voluntary donors (0.27%) was less as compared to the replacement donors (0.60%) among the 16,520 HCV-positive donors studied by Thakral et al.[11], Kakkar et al.[19], from our institution noted that 94.7% of the donors were replacement donors. This probably reflects a basic lack of awareness in the general population the presence of misconception and fear associated with donating blood, the lack of health education and the indifferent attitude of the health sector. The need to shift the burden to voluntary blood donation cannot be overemphasized.

Our study reveals an average overall prevalence of HCV antibodies in blood donors' serum as being 0.20% which is significantly lower than other

regions of India. The reason for this may be either a particular geographical distribution or declining rate of HCV positivity in healthy population. The wide variations of HCV seroprevalance in different studies in India might be due to the use of different generation of ELISA test kits, having different sensitivities and specificities. Various studies have reported an international HCV prevalence range of 0.42–1.2%.[17] Various studies in India about the seroprevalence of HCV have shown data ranging from the lowest (0.31%) in the study by Bhattacharya et al in 2007[10] to the higher one of 1.09% (Gupta et al, 2004).[39]

Limitations

The major limitation of our study is that there was no previous data available from Dewas, Madhya Pradesh for comparison and analysis of trends. Hence, we recommend for future studies with larger sample size to look into the trends of TTIs from this geographical area.

Conclusion

Blood transfusion is an integral and life-saving procedure of modern medicine, but simultaneously it carries the risk of transmitting the life threatening transfusion transmissible infectious. HIV, hepatitis B, and hepatitis C are major public health problems in developing countries. They are transmitted parenterally, vertically, or through high-risk sexual behaviours and can cause fatal acute and chronic life threatening disorders. Blood transfusion is a potential route of transmission of these TTIs. Stringent donor selection, proper counseling and deferral/self exclusion may reduce the seroreactivity in donated blood and wastage of resources. Possibilities of transfusion transmitted infections were more with replacement blood donors in comparison to voluntary blood donors. Presently the safety of blood for transfusion is maintained by careful selection of voluntary donors and performing the mandatory screening for transfusion transmissible infections (TTI) as meticulously as possible.

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