

Prevalence of positive serology for HBV, HCV, HIV infections amongst blood donors: A tertiary care center experience

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Abstract

Background: Various studies of blood product transfusion transmitted infections (TTI) documented a prevalence of 0.32% human immune deficiency virus (HIV), 1.61% hepatitis-B virus (HBV) and 0.73% hepatitis-C virus (HCV) infection positivity. We carried out a retrospective study to evaluate the prevalence of HBV, HCV, and HIV seropositivity amongst the voluntary blood donors in our blood bank (BB) over a period of 2014 to 2018.

Material and Methods: Blood samples of donors were collected under all aseptic and anti-septic precautions in accordance to guidelines laid by the Drug & Cosmetics Act, 1945. 4 ml blood was collected in gel-clot activator vacutainer and ELISA was performed for anti-HIV, HBV, HCV using fully automated ELISA analyzer.

Results: Out of 34523 donors, 34134 (98.9%) were males and 389 (1.1%) were females. The overall prevalence rate of TTI was 2.54% (879). Among these,

seropositivity for HIV, HBV and HCV were 0.43%, 1.6% and 0.5% respectively.

Conclusion: TTIs testing has vital role to provide safe blood and blood components. This testing also helps to prevent TTIs in community by early diagnosis and management.

Keywords: Blood bank, blood products, testing, transfusion transmitted infections, donor

Introduction

Over the last decades, there were significant changes in both national blood policies and the methods used in blood collection and screening issues emphasizing the safety of the blood transfusion services on the discovery of Human Immunodeficiency Virus (HIV), which could be transmitted by blood transfusion^[1]. There is an increased awareness in estimating the risks of transfusion-transmitted infection. Nowadays several layers of safety checks are practiced to eliminate the risk of transmission of infection due to blood transfusion. First, the donor pool which should be purely voluntary. Second, Donor education by providing printed material containing information about blood donation. Third, laboratory testing of donated blood units. Finally, donor notification procedure and provision of self- exclusion for donors who are ready to donate blood under peer pressure however they believe that their blood donation may provide a risk to transfusion recipients. Blood supply can be safe by following these multiple layers of screening and testing. An accurate estimation of Transfusion transmitted infection (TTI) risk is an important tool for physicians to make informed decisions about whether to receive an allogeneic transfusion or to select an alternative therapeutic option^[2] Even if we test each donated unit of blood for viral infection marker, there is no absolute exclusion of TTI infection due to the window period

limitation. There are three inevitable transfusion risks. First is the Limitation of a test not to detect in the early-stage: window period. The second is the existence of a chronic carrier state and the last one is an Error in performing the test.

Various pathogens are responsible for TTIs. But the emphasis is given to HCV, HBV, and HIV only due to higher prevalence compared to other infections and chances of morbidity

The study for the prevalence of TTI marker is a need of time for selection of blood donors from a specific population group to provide safe blood transfusion to the community

Material and Method

We carried out a retrospective study to evaluate the prevalence of HBV, HCV, and HIV seropositivity amongst the voluntary blood donors recruited in 'Institute of Kidney Diseases and Research Center - Institute of Transplantation sciences (IKDRC-ITS) blood bank (BB) from year 2014 to 2018. Analysis was performed by database from Blood Bank Data Management Software (BDMS). This database contains information of 36907 blood donors (either voluntary or replacement donors) came voluntarily for blood donation at our institute blood bank as well as institutional blood donation camp. Before blood collection from the volunteer donors, two-level of screening was performed which included, (1) Pre-donation (Donor deferral by counseling): We counseled blood donors and made them aware about the eligibility and deferral criteria for blood donation. Then blood donors were given 'donor registration form' containing questionnaire according to NBTC guideline. We performed brief medical examination of donors. We excluded those who were engaged in behavior deemed at risk for transfusion transmissible infections (TTIs)

such as tattooing, drug abused and multiple sexual partners(2)Post Donation phase of screening (TTI testing) : It involves laboratory testing of the donated blood for HIV, HBV and HCV infection, Syphilis and Malaria.

Blood samples of donors were collected in EDTA and Plain Vacutainer along with blood bag collection under all aseptic and anti-septic precautions in accordance to guidelines laid by the Drug & Cosmetics Act, 1945. ELISA (Enzyme Linked –immunosorbent Assay) was performed for HIV, HBV and HCV using fully automated ELISA analyzer.

Laboratory Testing

We performed all tests according to the instructions provided by the manufacturer and validated by standard operating procedures

HIV Serology

HIV serology was done by Green screen ULTRA HIV antigen-antibody reagents (Bio-Rad, France) using the semi-automated platform. This is fourth-generation enzyme immunoassays (EIA) that detect antibodies to HIV-I (groups M and O) and HIV-II as well as the HIV p24 antigen.^[4] According to the algorithm and policy laid down by National AIDS Control Organization (NACO), positive blood samples were analyzed twice again then interpretation of the result was done based on concordant two of the three.

HBV Serology

This serology testing was performed on the Evolis semi-automated platform with “Monolisa HBsAg ULTRA reagents”.^[5] It’s a fourth-generation EIA reagent detecting hepatitis-B virus surface antigen (HBsAg). According to NACO guideline positive blood samples should run twice again and interpretation of the result was done based on concordant two of the three.

HCV Serology

The testing for HCV infection was performed by Evolis semi-automated platform with “Monolisa anti-HCV PLUS version3 reagents”.^[6] It’s a third-generation EIA reagent that detects antibodies to the NS3 and NS4 regions of the capsid of the HCV. According to the NACO algorithm, there is a repetition of all initial positives samples in duplication, and interpretation of the result was done based on concordant two of the three.

Result

Out of 36907 donors, 34523 (93.5%) donors were accepted according to blood donation criteria^[7] Thus, 2384 (6.5%) donors were rejected either permanent or temporarily due to their medical condition [Table 1], past history of any disease, and medication. Male donors were more observed than female donors in our study. Total male donors in our study were 34134 (prevalence- 98.9%) whereas female donors were 389 (prevalence- 1.1%). Among this accepted 34523 donors, 4895 (14%) were voluntary donors including camp donors and 29628 (86%) were replacement donors [Table 2].

We have observed that total 897 (2.55%) donors out of 34523 accepted donors found reactive/positive for TTIs [Table 4]. HIV infection found in 149 (0.43%) donors, HCV infection reported in 175 (0.51%) donors and HBV infection seen in 555 (1.61%) donors [Table4]. Co-infection of HIV and HBV reported in 7 donors (0.02%), while Co-infection of HBV and HCV reported in 5 donors (0.014%).

Discussion

In developing and underdeveloped countries, TTI is a major risk factor for the safety of blood transfusion services due to window period infection of HIV, HBV, and HCV^[8]. The donor deferral rate of this study is 6.5

% [Table 1] which is almost in the range of other studies^{[9] [10] [11]}, Accepted donors were 93.5. Out of all accepted donors, voluntary donors were 14 % and replacement donors were 86% [Table 2]. As ours is a hospital-based blood bank replacement donor rate is quite high in this study as compared to other studies^{[12] [13] [14]}, Because of that reason donors are mostly relatives of patients who get service from our blood bank. In our study predominantly 98.9 % of donors are males followed by females with 1.1 % [Figure 3] which is almost similar or lower to different studies^{[15] [16] [17]}. This study showed that 2.55% of the accepted healthy blood donors were found seropositive for at least one of the Transfusion transmitted infection markers [Table 4]. This number falls within the range of seropositivity rate in donors in other parts of India i.e. 1.9% to 3.45%^{[18] [19]}. However, the seropositivity rate of 2.55% is considered quite high compared with other regions of India, posing great concerns about blood safety and promoting the need for stringent donor selection criteria and blood screening measures. It was also noted that 7 units (0.02%) of donated blood specimens had serological evidence of multiple infections with HBV and HIV as the most common concurrent infections, followed by HCV and HBV 5(0.014) [Table 5]. These co-infections should always be screened as a matter of priority. In this study, the prevalence rate of HIV infection in our center (0.43%) [Table 4] was quite higher than that in the general population (0.3%)^[20]. this observation is not consistent across different areas of India. HIV prevalence rate among blood donors from Western India (0.07) displayed a low prevalence than Northern (0.33), Southern (0.44), and Eastern (0.28) India. Thus, HIV prevalence rates among different regions in India were varying. HBV prevalence in our study is 1.61 which is the highest among other TTI

marker screened [Table 4]. Which is comparable to other studies.in india HBV is a well-recognized public health concern, The HBV vaccination program was implemented in June 2002 in compliance with international recommendations of vaccination to prevent and control HBV infection. After 2007-2008 HBV vaccination was provided for all neonates as a pilot project under UIP^{[21] [22]}.

The prevalence of HBV infection in India remains very high with approximately 40 million individuals having chronic HBV infection^[23]. To lower the seroprevalence of HBV infection among the donor population the Pre donation HBsAg rapid testing might be introduced for controlling risks. The prevalence rate for HCV infection in blood donors in our study was revealed to be 0.51% which falls within the range of the general population (0.5 - 1.5)^[24]. In 2002, the Government of India introduced a mandatory screening of donated blood for HCV. Moreover, in recent years, sensitive and specific detection techniques for anti-HCV antibodies have been introduced. All these measures lead to a dramatic decrease in HCV prevalence throughout India after 2002. The government also implemented a consistent national donor screening policy^[25].The safety of blood supply and transfusion in India has been greatly enhanced. However, all the rates of TTI positive donations observed in our study showed a decreased trend in the last year [Figure 4]. This decrease might be due to two reasons. Firstly, the methods used in blood screening tests have improved, leading to a decrease in the number of false-positive results. Secondly, the decreasing trend of TTI in the donated blood may be associated with the increased number of voluntary donors in the last year of the study. It has been well documented that voluntary blood donors always pose a

lesser risk of infectious donation than replacement donors.

Tables

Table 1: Accepted and rejected blood donors

Year	Total donors	Accepted donor	Rejected donor
2014	7610	7410	200
2015	7406	7230	176
2016	7442	6764	678
2017	7134	6535	599
2018	7315	6584	731
	36907	34523 (93.5%)	2384 (6.5%)

Table-2, Voluntary and replacement donors amongst accepted donors

Year	Accepted donors	Voluntary	Replacement
2014	7410	1395	6015
2015	7230	1270	5960
2016	6764	768	5996
2017	6535	819	5716
2018	6584	643	5941
	34523	4895 (14%)	29628 (86%)

Table 3: Gender distribution among accepted donors

Year	Accepted donors	Male	Female
2014	7410	7283	127
2015	7230	7150	80
2016	6764	6701	63
2017	6535	6488	47
2018	6584	6512	72
Total	34523	34134 (98.9%)	389 (1.1%)

Table4: Test result of TTIs in accepted donors

Year	HIV	HBsAg	HCV	Total
2014	15	74	4	93
2015	8	119	66	193
2016	36	106	22	164
2017	58	145	37	240
2018	32	111	46	189
Total	149 (0.43%)	555 (1.61%)	175 (0.51%)	879 (2.55)

Figures

Figure 1: Accepted and deferred blood donors

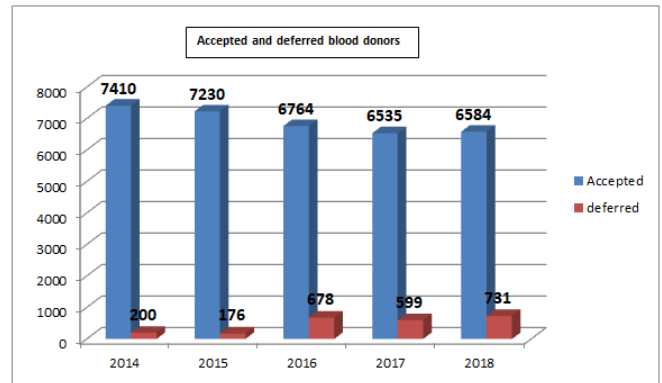


Figure 2: Voluntary and replacement donors amongst accepted donors

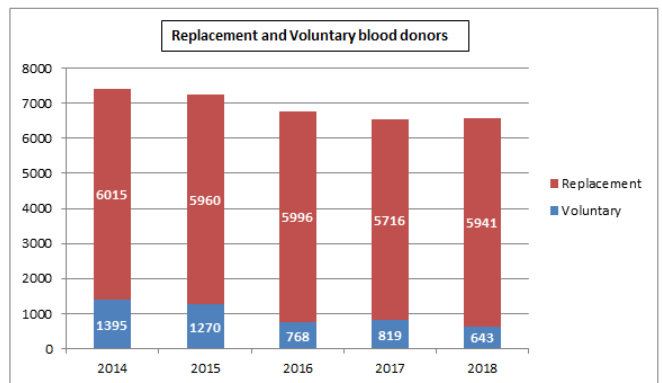


Figure 3: Gender distribution among accepted donors

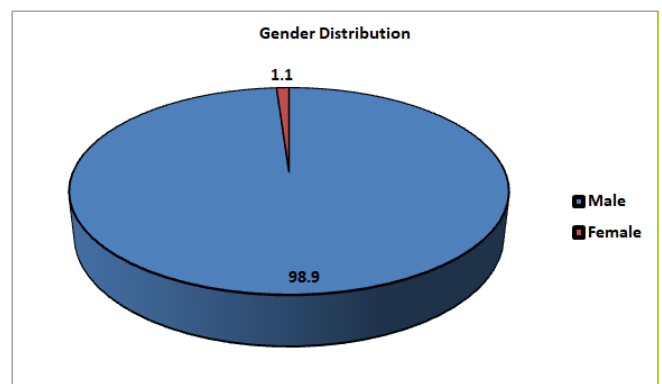
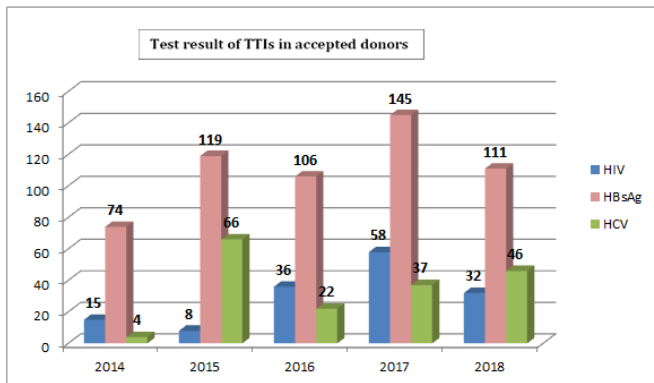


Figure 4: Test result of TTIs in accepted donors



Conclusion

TTI plays an important role in supplying safe blood and blood components for patient management. An additional advantage of identifying seropositive individuals also helps in the prevention of the spread of TTIs, early management, reducing the associated morbidity as well as mortality. Repeat voluntary donors are better candidates who are not engaged in risky behaviors before donations and can be tested negative at their prior donation to reduce the probability of blood infections in the window period. Moreover, the Majority of repeat donors wouldn't suddenly engage in high-risk behaviors. In order to strengthen the safety of the blood supply, not only should new donors be carefully recruited to take care of the quantity of the donation pool, but a cadre of previous donors should also be actively retained. In conclusion, the seroprevalence of certain TTIs seemed to be lower among blood donors than that within the general population of India as they are healthy individuals coming forward for blood donation. This is largely thanks to the effective system to pick donors and screen donated blood. However, hepatitis B and C were found more common. These were the primary threats to blood safety. The increasing trend of blood-borne infections in blood donors calls for more stringent measures.

Limitation of our study

Limitation of our study is that this testing can not provide absolute result during window period of TTIs. Means false negative result might be observed during testing. Sample size of voluntary blood donors are smaller compare to replacement blood donor sample size. Community spread of true prevalence of TTIs can't be known.

Future path

More sensitive screening methods like macromolecule testing should be adopted to detect TTIs earlier and reduce the risks related to window periods. It is highly considered to enhance donor recruitment procedures and increase the proportion of normal donors. Young people, higher educated population and former donors should be encouraged to donate blood to assist ensure a long-term safe blood supply.

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Abbreviations

BB- Blood Bank

BDMS- Blood Bank Data Management Software

EDTA – Ethylene Diamine Tetra-Acetic acid

ELISA- Enzyme Linked Immunosorbent Assay

IKDRC-ITS- Institute of Kidney Diseases & Research

Center – Institute of Tranplantation Sciences

HIV- Human Immunodeficiency Virus

HCV- Hepatitis C Virus

HBV- Hepatitis B Virus

HBsAg- Hepatitis B Surface Antigen

NACO- National AIDS Control Organization

NBTC – National Blood Transfusion Council
TTI- Transfusion Transmitted Infection
UIP – Universal Immunisation Programme

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