

Evaluating Prevalence Of Transmissible Infections In Hilly Area Blood Donors: HIV, HBV, HCV And Syphilis

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Abstract: **Introduction:** Blood transfusion plays an important role in a healthcare setting; however, Transfusion Transmitted Infections have a major impact on its effective usage in therapeutics. Transfusion Transmitted Infection (TTI) is an infection which is transmitted from person to person by parenteral administration of blood and blood products. Owing to the severity of TTI's World Health Organisation (WHO) made pre-transfusion blood tests like Human immunodeficiency virus (HIV), Hepatitis B virus (HBV), Hepatitis C Virus (HCV) and Syphilis as mandatory. **Aim:** The aim of the study is to determine the prevalence of HIV, HBV and syphilis among blood donors in a tertiary care hospital in hilly area. **Study subjects, settings:** The study was conducted on 343 blood donors from July 2017 to September 2017 who attended blood bank at District Hospital, high altitude area in India, after obtaining consent. **Method:** The blood samples were collected aseptically from voluntary blood donors of age groups 18-50 years and screened for HIV, HBV, HCV and Syphilis in the blood bank. Tests were performed by using (NACO) approved ELISA kits – HIV Gen 3 (Transasia Bio-Medical Ltd., Daman, India), SEN HBsAg (Transasia Bio-Medical Ltd., Daman, India), HCV Gen 3 (Transasia Bio-Medical Ltd., Daman, India), Syphilis – J. Mitra & Co/ Tulip group). **Statistical analysis:** Data collected was tabulated in Microsoft Excel and results were expressed as percentage. **Results:** Out of the 343 donors, one donor was HBsAg positive (0.3%) and another donor was VDRL positive (0.3%). The prevalence of HBV and Syphilis is comparatively more than HIV. and HCV. **Conclusion:** The seroprevalence of these transfusion transmittable infections such as HIV, HBV, HCV and Syphilis was extremely low, so we can conclude that the prevalence of these infections is declining.

Keywords: Blood transfusion, transfusion transmittable infection, HbsAg, HCV, HIV, syphilis, prevalence.

INTRODUCTION

An inherent compound of healthcare is transfusion of blood and blood products. Blood donation is one of the most significant contributions that an individual can make towards the society. Blood donation is one of the best methods for a person to increase longevity from life threatening injuries or diseases, hence, it is considered a noble action. Hospitals are in constant need of blood during emergencies and surgeries. Transfusion of blood and blood components is a life-saving manoeuvre of patient management.

According to World Health Organization (WHO) Global Data- base on Blood Safety (GDBS) 2021, It is estimated that 118.5 million blood donations were made in the 171 countries during the reporting period. Countries in the low-income and lower-middle-income groups collected 2% and 24% of the global donations, respectively, though their populations represent 8% and 40% of the global population, respectively. Overall, an increase of 10.7 million blood donations from voluntary non-remunerated donors between 2008 and 2018 was observed in the 119 countries.^[1] The epidemiology of these infections in the community is obtained by Evaluation of the data of the seropositivity of TTI's among voluntary blood donors.

With every unit of blood, there is a 1% chance of a transfusion-associated problem including TTIs^[2]. Globally, approximately 240 to 340 million people have been infected with hepatitis B Virus (HBV) well more than 170 a million people showing chronic hepatitis C virus. India has approximately 10- 15% of the HBV carrier of the world and 0.5- 1.5% of the HCV carrier of the world, respectively^[3]. During blood donation, some of the common viral infections, are hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV). Morbidity and mortality resulting from the transfusion of infected blood have far reaching consequences not only for the recipients themselves but also for their families, communities and the wider society^[4].

A transfusion transmissible infection (TTI) is any infection that is transmissible from person to person through parenteral administration of blood or blood products^[5]. Transfusion therapy is a well-established treatment in various medical and surgical procedures, ^{blood} is one of the major sources of transmission of hepatitis B, hepatitis C, HIV, syphilis, and many other diseases^[6]. This has necessitated formulation of National Blood Policy and development of National Blood Program under National AIDS Control Programme (NACP)^[7]. As per guidelines of National AIDS Control organization (NACO) of India, it is mandatory to test each and every blood unit for HIV, HCV antibody, HbsAg, Syphilis and Malaria^[8].

Worldwide transfusion medicine has a great public health importance. Indian guidelines require routine screening of blood and its components for the five most common TTI's in all the blood banks. These include HIV, HBV, HCV, syphilis and malaria^[9].

With every unit of blood, there is 1% chance of transfusion associated problems including TTI. ^[10] The Indian subcontinent is classified as an intermediate HBV endemic (HBs Ag carriage 2-7%) zone and has the second largest global pool of chronic HBV infections. India has a population of more than 1.2 billion with 5.7 (reduced to 2.5) million HIV positive, 43 million HBV positive, and 15 million HCV positive persons^[11].

For monitoring the security of the blood supply and assessing the effectiveness of the screening methods now in use, accurate estimations of the risk of TTIs are crucial. Monitoring the incidence of transfusion transmitted infections in blood donors is important for estimating the risk of transfusion and optimizing donor recruitment strategies to minimize transmission. Evaluating trends in blood donor infectious disease rates is essential for monitoring blood supply safety and donor screening effectiveness^[7].

The economic cost of the failure to control the transmission of infection includes increased requirement for medical care, higher level of dependency, loss of productive labour force on already overstretched health and social services on nation's economy^[12].

HBV and HCV infections cause serious public health problem that ultimately leads in fatal condition like liver cancer, ensuring blood safety it is suggested to launch programs at local level to provide awareness about safe sexual behaviours and prevention on Drug abuse and moreover the individual should strictly follow preventive measures against these infections^[13].

Screening of blood is now mandatory for many diseases and is undertaken routinely in blood banks^[6]. WHO suggests that all activities associated to blood collection, testing, processing, storage, and distribution be matched at the national level through effective organization and national blood policy. Systematic screening of all donated blood for infection also helps in addressing TTI, in contrast, in many developed countries, these interventions are applied uniformly, and the risk of TTI found to be low^[11].

With the ability of pathogens to evolve rapidly, continuous redefining of testing standards and laboratory techniques is paramount for maintaining a safe blood supply^[14].

MATERIALS AND METHODS

- **Study Period:** This cross sectional study was conducted on all blood donors from July 2017 to September 2017 who attended blood bank at District Hospital, Hilly area, India, after obtaining ethical clearance from the institution.
- **Study Design and Participants:** The blood samples were collected aseptically from voluntary blood donors and screened for HIV, HBV, HCV and Syphilis in the blood bank. Universal sampling method was used to include all the blood donors who donated blood to the blood bank of age group 18-50 years. Institutional Ethical Committee Clearance was taken (Reference: KOIMS/IEC/13/2018- 19). The recorded information was analyzed. All blood donors during the above-mentioned period were included.
- **Data collection:**
 - All the blood donors included in the study should satisfy the criteria for blood donation as per Drugs and Cosmetic Act 1940, supplemented by the Technical Manual 2003 (Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India).
 - All the information regarding blood donors like demographic data, weight, hemoglobin status, history of previous hospitalization, blood transfusions, tattooing, history of exanthematous fevers in the last 6 months was taken.
 - Weight, pulse rate, blood pressure, temperature will be recorded manually and stored using appropriate electronic devices.

- A written informed consent shall be taken from each donor before the blood donation. Consent was in English and local vernacular Kannada language for the convenience of the patient which included information about donors general health, previous blood donation or transfusion history, history of ailments like allergy, renal diseases, endocrine diseases, heart diseases, high/low blood pressure, sexually transmitted diseases, current or past febrile illness, weight loss, infections like tuberculosis and malaria, unusual or excessive bleeding, drug history, tattoo piercing, dental treatment, sexual history and risk behaviours.
- Proper sterilization and other precautions shall be taken during the blood collection and blood units shall be stored by appropriate methods.
- Tests were performed by using National AIDS Control Organization (NACO) approved ELISA kits.
 - i) HIV – HIV Gen 3 (Transasia Bio-Medical Ltd., Daman, India)
 - ii) HBV – SEN HBsAg (Transasia Bio-Medical Ltd., Daman, India)
 - iii) HCV – HCV Gen 3 (Transasia Bio-Medical Ltd., Daman, India)
 - iv) Syphilis – (J. Mitra & Co.)
- **Inclusion Criteria:** All blood donors were included in this study.
- **Exclusion Criteria:** Weight less than 50 kg, age less than 18 years, anemic, apparently unhealthy or malnourished donors, donor with history of jaundice or asthma, high risk behaviour individuals like history of unsafe sexual intercourse or drug abuse and donors with past history of syphilis, malaria, HBV, HCV or HIV excluded.
- **Statistical Analysis:** The data collected was entered into Microsoft Excel. Categorical data was expressed in terms of rates, ratios and percentage.

OBSERVATION AND RESULTS

In this study, there were 343 voluntary blood donors in a period of three months i.e., July 2017 to September 2017. The donors were given counselling before blood donation. Among the donors, 317 (92.41%) were male donors and 26 (7.41%) were female donors as shown in Table 1.

Table 1: Gender wise distribution of the donors:

Month (2017)	Total donors (100%)	Gender	
		Male	Female
July	100	93	7
August	135	130	5
September	108	94	14
Total		317 (92.41%)	26 (7.41%)

Majority of the participants 156 (45.48%) were in the age group 18-25 years, followed by 141 (41.10%) were in the age group 31-40 years. A relatively less population 37 (10.78%) and 9 (2.62%) were in the age group 41-50 years and 51-68 years, respectively as shown in Table 2.

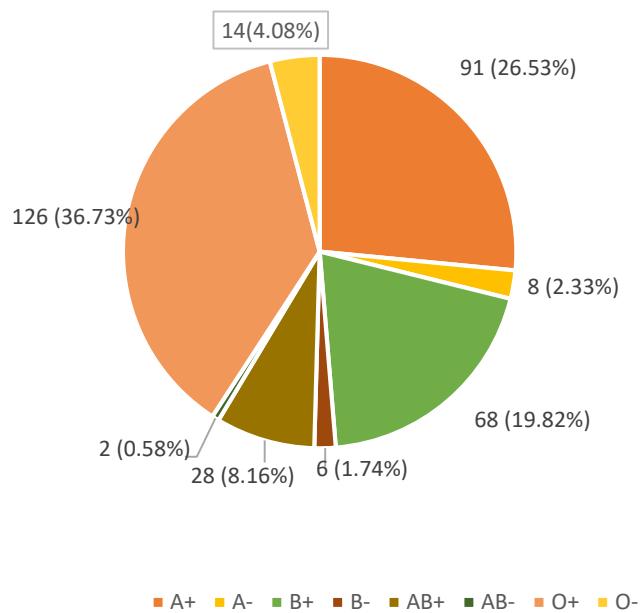
Table 2: Age wise distribution of the donors

Age	Number of Donors
21-30	159 (45.48%)
31-40	141 (41.10%)

41-50	37 (10.78%)
51-60	6 (2.62%)

The blood group distribution showed that the maximum number of donors 126 (36.73%) were O positive, followed by A positive with 91 (26.53%), B positive with 68 (19.82%), AB positive with 28 (8.16%), O negative with 14 (4.08%), A negative with 8 (2.33%), B negative with 6 (1.74%) and AB negative with 2 (0.58%). This data has been interpreted in Pie chart 1 below.

Pie chart 1: Blood Group distribution of participants



All the donor blood samples were tested for applicable serological tests and the screening reports were evaluated. Out of the 343 donors, one donor was HBsAg positive (0.3 %) and another donor was VDRL positive (0.3%). According to this study the presence of HBV and Syphilis is comparatively more than HIV and HCV.

Table 3: Distribution of positive donors for TTIs

Transfusion Transmittable Infections	Number of positive donors
HIV	0
HBV	1 (0.3%)
HCV	0
Syphilis	1 (0.3%)

The relationship between the gender of the blood donors with respect to HBV and syphilis infection was studied. This information is presented in table 4.

Table 4: Relation between gender and HBV and Syphilis

Gender	Count		HBV			Syphilis		Total
			Positive	Negative	Total	Positive	Negative	
Male	Count	1	316	317	1	316	317	

Sex		% Within Sex	0.3%	99.7%	100.0%	0.3%	99.7%	100.0%
Female	Count	0	26	26	0	26	26	
	% Within Sex	0.0%	100.0%	100.0%	0.0%	100.0%	100.0%	
Total	Count	1	342	343	1	342	343	
	% Within Sex	0.3%	99.7%	100.0%	0.3%	99.7%	100.0%	

- Blood bags with positive serological tests were considered positive for transfusion-transmissible infections (TTIs). The bags were segregated from other blood units to prevent accidental use. Needle was cut off Discarded in a designated sharps container. Filled blood bags was treated by autoclaving to ensure that any remaining pathogens are destroyed.

DISCUSSION

Voluntary and Replacement donors

All the donors recorded were voluntary blood donors. Blood donations are safe when it is voluntary, non-remunerated and from low-risk populations. For a safe blood service in our country, where comprehensive laboratory tests are neither possible nor pragmatic, it is best to switch over to 100% voluntary donations, as it is now established that only voluntary non-remunerated regular donation is the safest. Replacement donors conceal medical history which is a great threat to safety of blood transfusion. Donor blood was collected in routine blood donation camps held. This trend can be seen in a study conducted in Tripura where Among all donors, 91.8% was voluntary donors and 8.2% was replacement donors similar to a study by Hans R et al, which showed 83% voluntary donors and 17% replacement donors^[15]. implicating a developing blood donation awareness among the public^[4].

The paramount concern in transfusion services currently is increased seropositivity among Replacement Donors for HCV, HIV, HBsAg and syphilis. A noticeable number of replacement donors harbour HIV, HBV, HCV, Malaria and Syphilis infections. So strict selection of donors and proper testing of donor's blood by using standard method is highly recommended to ensure safety for recipient^[16].

Gender and Age wise distribution of the donors

A large percentage of the blood donors were males 317 (92.41%) while the female donors accounted for 26 (7.41%). The probable reason may be the cultural and physical health differences in the society, which may have prevented women from blood donation. Another reason could be due to poverty and poor nutritional status of women because of which they did not meet the required criteria set for blood donation.

Higher proportion of male donors was observed in studies conducted in Ethiopia, Vadodara and Itahari, which concurred with the results of this study^[5,7,13,]. Similarly, a study by Gupta D M et al, showed predominance of males (84.62%) when compared to females (15.38%)^[17].

Out of the 343 donors, majority 156 (45.48%) of the donors were in the age group 18-30, followed by 141 (41.10%) in the age group 31-40 years. A report by Shah M et al, the majority of donors, i.e., 48 (69.8%) positive samples were from the age group 18-30 years. Next common age group was 31-45 years which were 60 (28.3%) which is comparable with our study^[11]. Blood donation camps are also keen in receiving young donors due to many benefits. Nowadays, youngsters take part in blood donation camps and programs actively.

According to a study done by Naskar S et al, Seroprevalence increased after the age of 30 years, though not linearly, with the highest rate (3.2%) recorded in the 31-40 years and 51-70 years age, age and gender of donors seem to be important factors affecting it^[18].

Blood group distributions of participants

It was observed that most of the donors (36.73%) had O positive blood group, followed by A positive with (26.53%) and the lowest (0.58%) were AB negative. A study conducted by Sethi B et al, showed most common blood group among units collected was A followed by B, while least common was AB, similar to our study, which may be attributed to genetic or environmental factors. Maximum seropositive cases (27/83) were found among units with blood group A, while the seroprevalence rates for HBsAg, HIV and HCV were highest in blood groups AB, B and B, respectively^[19], which was not found in our study.

TTI status of participants

Among the total 343 voluntary blood donors, one case of HBV and Syphilis infections each were recorded positive between July 2017 to September 2017. The prevalence of these two infections is low. HIV and Syphilis infections had zero prevalence during the study period. The zero prevalence could be due to small sample size, less study period and regional differences.

Our study showed a seroprevalence of HBV as 0.3%. Higher prevalence rate has been recorded in other studies, which may be due to a higher sample size, longer study duration and the variation in the number of blood donation in different demographic regions. In a study by Bhaumik P et al, HBV prevalence was found to be 1.2%^[4], while the prevalence was found to be 1.06% in a study by Shah M et al^[10]. Seroprevalence of HBV was 0.66-12% in Mysore district^[9]. The prevalence of HBsAg seropositivity of 0.85% was recorded in Vadodara^[7] and in Western Maharashtra it was 1.79%^[20]. All these studies showed a higher prevalence than our study.

Though there was no prevalence of HCV in our study, Shah M et al. a smaller rate of this infection 0.14% was found among the blood units^[10]. Similarly, Seroprevalence in Mysore district was recorded as 0.5-1.5%^[9]. In a study conducted by Sharma D.C et al, HCV prevalence was 0.24%^[12].

In Mysore district, prevalence of Syphilis was found to be 0.85- 3% which is more than our study^[9]. whereas a study by Fatima A et al, was 0.03%^[21]. In Darjeeling, seroprevalence was found to be 0.65%^[21]. The study by Sul V.G et al, showed a prevalence of 0.13% which is much less than our study^[20].

Prevalence of HIV in our study was zero. A study by Shah M et al, got only 29 positive case of HIV (0.2%)^[11]. In Vadodara, overall prevalence of HIV seropositivity (0.30%) was higher than positivity annual report of GSACS, 2010-11, in which it was 0.15%^[7]. In a study by Chattoraj A et al, the overall prevalence of HIV seropositivity was 0.13%^[23], which is comparatively low.

A correlation between the gender of the blood donors and seroreactivity of TTIs was attempted to be found. No significant relation could be attributed to their gender considering lower number of female donors. In a study by Prakash P et al, the majority of the donors in the present study were males (98.95%) with a very small percentage were (1.04%) of female donors^[9]. In a study done at Gwalior by Sharma D C et al, showed similar increasing trend of voluntary blood donation with male predominance^[8].

It has been recognised that it is difficult to establish uniform serological testing which allows for consistently accurate antibody identification and which can be adapted to suit clinical expediency, which necessitates a need for standard single system (ELISA, NAAT) that encompasses cost effectiveness, ease of use, and accuracy^[24].

Nucleic acid amplification technology [nucleic acid testing (NAT)] for transfusion-transmissible viral infections (TTVIs) has added a highly sensitive additional layer of safety to the blood supply, addition of NAT with serology testing improved the blood safety by picking up 50 donations/year which were missed by serological method and thus interdicting possibility of 150 TTIs annually^[15].

The lack of uniformity in the blood transfusion services and transfusion protocols in a diverse country like India makes blood safety challenging. Hence it requires a laboratory diagnostic method that is cheap, durable, easier to perform with higher sensitivity. NAT is one of the method which has a higher sensitivity and NAT as a technique if used for blood unit screening will have high impact in enhancing blood safety^[25].

However, it has been argued that NAT testing for India may not be the solution for blood safety as the 4th generation advanced antigen antibody combined serological tests are becoming available, they will significantly shorten the window period^[26].

CONCLUSION

The seroprevalence of transfusion transmittable infections (TTIs) in our study is not comparable to the national average, because of the shorter duration of study period of this research when compared to other studies conducted which have lasted years. A larger study group would be required to produce more substantial estimates of the prevalence of these infections. Other potential factors like regional trends, demographics, or testing methods also affects the results of the study.

Though the social and demographic information has been collected in this study, more insight would be helpful in assessing the factors responsible for HIV, HBV, HCV, and Syphilis infections.

For significant reduction of the transmission of transfusion related infections, practice of replacement donors must be phased out and blood centers and camps should aim at achieving 100% voluntary non-remunerated donors as ideated in National Blood Policy formulated by National AIDS Control Organization (NACO).

Proper awareness campaigns, vaccination, medical examination of donors and stringent screening of donors, disease surveillance, proper use of blood without wastage, development and application of technologies like Nucleic Acid testing (NAT) along with ELISA and other preventive measures must be followed. Transfusion transmittable infections are, indeed, worrisome but common challenges of blood transfusion can be averted by the above mentioned strategies.

Keeping in mind the psychological implications of this study, it is essential to deal with the stigma that is associated with some transfusion transmittable infections like HIV and Syphilis. Many at times, blood donors tend to hide their status to prevent embarrassment in society. By accepting these individuals, providing awareness campaign, proper education and treating them as equals would help prevent transmission of these infections to innocent recipients.

The Government as well as the Healthcare community must be aware of the emergence of newer infections (cytomegalovirus, HTLV, Zika virus, Anaplasma) that could be transmitted through blood transfusion as tests for the detection of these infections may not exist or may not be utilized during routine testing. The policies thus laid down must be strictly followed by the healthcare community and this must be ensured by the Government of India.

With almost 9.8 million units of yearly collections and 84% voluntary donors, India is expected to bang on the WHO target of 100% voluntary donations by 2020, much before due date [22]. The potential risk of spread of these infections will always exist. Hence, our focus must be aimed at substantial minimization until the risk is eradicated.

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CONFLICT OF INTEREST:

The authors declare that there are no conflicts of interest associated with this manuscript.

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