



ORIGINAL RESEARCH PAPER

Pathology

AN OBSERVATIONAL STUDY OF SEROPOSITIVITY RATE AMONG BLOOD DONORS AT A TERTIARY CARE CENTRE IN BIHAR, INDIA

KEY WORDS: Voluntary blood donors, HIV, HBS, HCV, Syphilis

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ABSTRACT

Introduction: The demand for blood and blood product has always fulfilled and followed by the process of best recruitment of donors. Voluntary blood donors are most suitable for donation of blood and blood products because of they have carried more good physical and mental status comparisons to other donors. Screening of blood donors always provides a unique opportunity to study prevalence of various infectious diseases in general population.

Material and Methods: There is an observational study which was carried out among 2657 healthy blood donors from April 2018 to mid-January 2019 at blood bank AIIMS, Patna. Serum sample of donors were screened for HIV 1 & 2, Hepatitis B, Hepatitis C viruses and Treponema pallidum (syphilis bacteria) using ELISA kits . Tests were performed according to standard manufacturer's instructions. Blood samples labeled seropositive on repeat testing were discarded.

Result: Out of 2657 donors, 106 were seropositive. The prevalence of seropositive donor was 4.3% among healthy person of which HBS 2.25 % (60),HCV 0.4% (11),HIV 0.4 % (11) and syphilis 0.94% (25).

Conclusion: Notification of all seropositive cases should be followed by treatment modalities and strong and effective psychological mental interventions. Screening by nucleic acid test assay (NAT) is an option during incubation period. Biometric and universal identification by AADHAR should be mandatory to identify professional and missed out donor.

INTRODUCTION

The demand for blood and blood product has always followed the process of best recruitment of donors. Voluntary blood donors are more suitable for donation of blood and blood products because of they have better physical and mental status in comparison to other donors. WHO has a defined broad spectrum criteria for selection of blood donor .The following criteria are required for healthy donor selection :

1. Donor should be free of infection of hepatitis ,malaria, HIV/AIDS, and venereal disease or other infections.
2. Donor should have no history of unexplained weight loss, repeated diarrhea, swollen glands, or continuous low grade fever for 6 months.
3. Donor should be free of following major diseases such as heart disease, lung disease ,chronic nephritis, tuberculosis, abnormal bleeding tendency, jaundice, typhoid, schizophrenia, cancer/malignant disease, allergic disease, sexually transmitted disease, epilepsy ,diabetes on insulin, fainting spells, hepatitis B/C, malaria ,endocrine disorder, and asthma.
4. There should be no history of minor surgery such as dental extraction, ear piercing, or tattooing within one month or any major surgery within six months.
5. There should be no history of drug ingestion such as antibiotics, steroids vaccine, aspirin, alcohol or any other medication within 72 hours .
6. General physical examination criteria include weight (>45kg),height, pulse (60 to 100 /min) Haemoglobin (>12.5 g/dl) BP(diastolic 60to 89mmhg,systolic 100 to 139 mm hg) ,temperature(should have no fever).

Screening of blood donors provided a unique opportunity to study prevalence of various infectious diseases in general population. With the above objective in mind, we conducted an observational study at Blood Bank AIIMS, Patna to know prevalence of seropositivity of common infectious disease among healthy voluntary donors. Donors were screened using a strict questionnaire followed by physical examination. The parameters being evaluated included those of age, sex, occupation, demographic locality, physical examination, medical examination, history of communicable disease and others.

MATERIAL AND METHODS

This is an observational study which was carried out among healthy blood donors who presented at blood bank of AIIMS, Patna from April 2018 to mid-January 2019. Approval from institutional ethics committee was obtained. A total of 3786

donors were screened ,out of which 2657 donors were eligible for donation. Informed & written consent was taken from all participants. Serum sample were screened for HIV 1 & 2, Hepatitis B, Hepatitis C viruses and Treponema pallidum (syphilis bacteria) using ELISA kits from lab system{ 4th generation Meril, s.d RPR Carbogen}. Tests were performed according to standard manufacturer's instructions. All reactive samples were retested as per direction of national AIDS control organization {NACO} guideline. Blood samples labeled seropositive on repeat testing were discarded. Test results data were assimilated and statistical analysis was done on them. Chi-square test was used and p-value calculated.

RESULTS

Table 1: Distribution of seropositive and seronegative donors

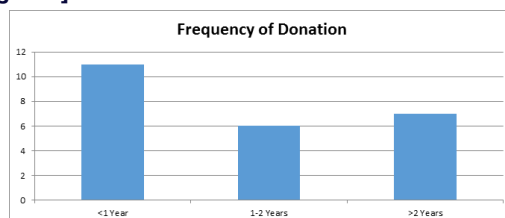
	Seropositive	Seronegative	Chi-square value	P-value
Male	102	2379	1.4503	0.22848
Female	4	172		
Married	66	2313	1331.147	<0.0001
Unmarried	40	168		
Rural	72	2307	91.3211	<0.0001
Urban	33	168		
literacy			173.0403	<0.0001

• P value <0.001, Highly significant, <0.05 Significant, >0.05 Insignificant

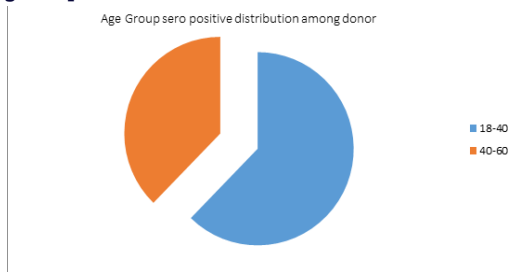
[Table 2]

sex	Seropositive	Seronegative	Total
male	102	2379	2481
female	4	172	176
total	106	2551	2657

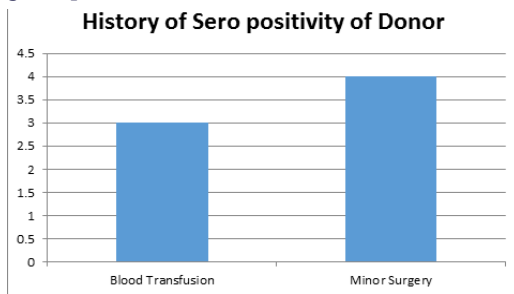
[Figure 1]



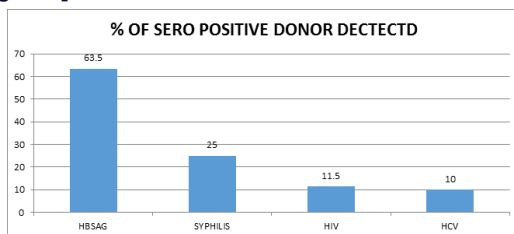
[Figure 2]



[Figure 3]



[figure 4]



- Multivariate analysis was conducted. A total number of 3786 donors were screened, among them 2657 were recruited for donation.
- Total collection included 2481 males and 176 females [**Table 1 and 2**]. Among male donors 102 were seropositive while in females 4 cases were recorded .Statistical analysis shows p value=.2284 which was not significant. Female population have showed very less number of donation .
- According to our study's finding 66 donors were married while 45 were un married. [**Table 1**] . p value was .1331 which was significant to this study. From all donors one third donor were unmarried according their marital status records.
- Out of total seropositive donors, 73 belonged to rural areas where rest 33 were from urban areas [**Table 1**].statistical study showed p value =.91 which was significant. That means Remote areas had greater lack of awareness in comparison to urban areas .from the records of literacy one third donors had performed thumb impressions instead of performing signature and they were resident from rural demographic division.
- Among all seropositive donors, 24 had history of blood transfusion within past 3 years.[**Figure 1**] Hence, they probably acquired infection within this 3 year period. 11 donor has been showed last history of blood donation within a year, 6 donors have been performed the donation between 1 to 2 years, and 7 donors had showed last history of donation more than last 2 years. This result also shows significant source of infection between these time periods.
- Most of the donor who had donated were 18 to 65 years age and age group between [18 to 40] shows highest prevalence of seropositive reactivity.[**Figure 2**]. Over all younger donors in our study had contributed to two third of total donation .Most peak aged of seropositive cases recorded were in 20 to 30 aged group population, and all donors were male.

- from the past history of contact or transfusion or transmissions, out of 7 donors,3 had reveled a history of blood transfusion in their past, and 4 had history of minor surgery one year back at remote area which indicate the source of acquired infection.[**Figure3**]
- Out of total donors, 106 were seropositive and prevalence of HBV,HCV,HIV and Syphilis reactivity was 60(2.25%), 11(0.4%),10(0.4%),25(.98%) respectively,which indicate highest prevalence of HBV(60%) which is 6 times more than HIV and HCV .[**Figure 4**]
- Co-infection of HIV+SYPHILIS were noted among 4 donors, and HBV+HCVinfection was seen in 2 donors,both males.

DISCUSSION

The Best measures to prevent the transfusion transmitted infection chain is by following transfusion screening chain -

- Donor eligibility - for best mode of finding a healthy donor
- Skin preparation- for reducing the numbers of skin flora on the puncture site
- Storage - for optimal temperature handling and storage of various products.
- Transfusion transmitted test- by valid standard methods^[1]

These preceding steps are followed to measure the transfusion transmitted infection incidence. We follow similar steps in our institute. On the similar parameter study by florian bhil² showed the result HIV in 1 in 213500,HBV in 277000,HCV in 1930000 and bacterial infection in packed red blood cell, 1 in 38500 in US population. Similar Comparative studies show the prevalence of transfusion transmitted infection HIV,HBV,HCV and in different populations³.

[Table 3]

HIV	HBV	HCV	SYPHILIS	AUTHOR & YEAR
0.8%	0.24%	0.001%	0.008%	Tulica C et al (2014)
0.162%	0.977%	0.108%	0.234%	Nirala S et al(2013)
0.14%	0.38%	0.06%	0.14%	Pragnesh j. patel (2015)
0.19%	0.63%	0.02%	0.02%	Bhawana S et al (2014)
0.4%	2.25%	0.4%	0.94%	Our study

Comparative studies shows the prevalence of transfusion transmitted infection HIV, HBV, HCV and Syphilis in different populations Prevalence of transfusion transmissible infection in different studies from India

[Table 4]

Study duration	Author	HIV	HBV	HCV	SYPHILIS
2006-2011	Dhar G ⁴	1.10%	0.8%	0.11%	0.13%
2011-2016	Davendrs S ⁵	.1135%	1.744%	1.503%	0.093%
2018-2019	Our study	0.4%	2.25%	0.4%	0.94%

Our study shows out of total 2657 donation HIV [11], HBS[60], HCV[11] and syphilis[25].A similar study on 15322 donors was done by Urveshi⁶, out which seropositive cases were HIV[47], HBS[284], HCV [84],and SYPHILIS were 84.

HBV

Genomic distribution of HBS genotypes is classified into 7 genotype,i.e. A-G. Genotype A (Aa, Ae) is identified in India⁷.World prevalence of GENOTYPE A is1.2%. The prevalence of chronic HBV infection varies geographically from high (>8%), intermediate (2-7%) to low prevalence (<2%) in world data⁷. Our Study shows prevalence in intermediate range with a prevalence of 2.5%.A study by Gautam et al showed mostly genotype D prevalent in India followed by genotype A .An observational study showed 1.2% prevalence of seropositivity of HBV among voluntary donors.⁸

A study done in 2001 shows prevalence carrier rate of hepatitis 1-5% in India . Post transfusion hepatitis B rate of about 10% is noted in India because of low viremia and mutant strain not detected by routine ELISA⁹. A study done in an era prior to hepatitis B donor testing showed the incidence of post transfusion hepatitis in the range of 300 cases per thousand units of blood transfused .The overall mortality by post transfusion hepatitis caused by hepatitis B virus may be as high as 12%¹⁰ .

Studies have shown that there is a rising trend of Hepatitis B infection prevalence among unmarried people, rural population, persons with history of blood contact i.e., surgery, transfusion and high risk behavior^{3,5,8,10} .

HIV

Statistics from NACO(2007) have showed Antenatal HIV prevalence of 0.25%³ in Bihar. A study which was conducted on prevalence of donor in HIV seropositivity showed 0.5% prevalence of HIV in their blood donors¹¹ while our study showed 0.4% . Studies of similar nature of HIV reactivity by western blot test showed a prevalence of 0.7% which was based on sequential immunoassay for counseling¹². A study which analysed the risk exposure of HIV showed blood transfusion share 9000cases of HIV per 10,000 exposure study. Other causes included needle sharing injection, drug use, and rest were high risk behavior¹³ , while, our study showed that 3 donors had past history of blood transfusion , 4 donor had history of minor surgery and 24 donor had exposure of blood donation at remote area ,hence they were seropositive for TTI. Global HIV and AIDS statistics 2018 fact sheet showed that 3.9 million people globally were living with HIV in 2017. New HIV infection have been reduced by 47% since a peak in 1996. In 2017 there were only 1.8 million new infection compared to 3.4 million in 1996.¹⁴

A study conducted in Delhi showed that blood transfusion has been the transfusion mechanism in 15% of total patient with HIV, and study showed 0.54% prevalence of HIV in blood donor.¹⁵ All of these studies show a falling trend of HIV infection.

SYPHILIS

Syphilis, out of the four has emerged as second highest sera conversion of this study, which describe eastern Indian population with a prevalence of .99% among all. While 6 year study of north India seroprevalence ranged from. 95% to 1.7% highest rate was detected in 2011¹⁶ . Our study shows total 25 case noted in donors, while 4 donor showed the presence of co infection with HIV. A study by Setith et al shows a statistically significant rise in prevalence of syphilis in HIV positive individuals¹⁸ . Sustained efforts for case detection and treatment are needed. An observational study showed Changes in sexual behavior, increased travel and migration and rapid increase in injection drug usage increases the condition of epidemicity of syphilis. In united states analyses revealed the seropositive prevalence of HIV with syphilis in male was 25.5% and 12.4% in females¹⁷ . A study of conducted in 2005 in Delhi showed that the prevalence of syphilis reactivity varied from .8 to 15 percent among blood donors.¹⁵
HCV

W.H.O data shows that HCV is prevalent in 3% of world population. Acute HCV infection is mostly asymptomatic. It may come out in nature accidentally or become chronic .The rate of chronic HCV infection is affected by age, gender, race and viral immune response of person. An estimated 10%-15% of HCV infected person will advanced to cirrhosis within the first 20 year¹⁵. Long term cohort studies still needed to characterize the risk factor profile that may predict eventual outcome of infection. Post transfusion hepatitis B/C is a major problem in India (10%) because of mutant strain undetectable by ELISA⁹ 0.4% prevalence among healthy donors has been reported in this our study .02% prevalence

has reported in patients attending a tertiary care hospital (parimalH.patel2017¹⁸).

Interlinkage of all blood centers who are involved in transfusion medicine practice including national or international hemovigilance systems is crucial for secure blood product management and prevention from known and emerging blood borne pathogen^{1,13}. Knowing the estimation of prevalence loads of seropositivity among the donor and notification and evaluation of notification measures is also needed and it will be further beneficial for stopping the spread of disease in population and help in exact mode of approach and treatment of seropositive donor. There were some drawbacks of our Study. No control group were studied. Study was conducted on target healthy population and hence comparison was not possible .Seropositive donor tracing was only conducted by donor registered address which was found inaccurate in some cases. Biometric identification and universal authentication of donors by AADHAR should be mandatory. Test screening by ELISA which may have missed the early incubation period infectivity should be replaced with newer advanced version of NAT assay.

CONCLUSION AND RECOMMENDATION

Good health practice requires awareness and reproducibility of health practice and their effective measurement and research. Notification of all seropositive cases should be followed by treatment modalities and effective psychological support . Screening by nucleic acid test assay (NAT) is an option during incubation period. Biometric and universal authentication by AADHAR should be mandatory to identify professional and missed out donor.

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