

Prevalence of Hepatitis B Virus Infection among Voluntary Blood Donors at a Tertiary Care Hospital Blood Bank - Tiruchirappalli

V Bagiyalakshmi¹, R Gopal¹, R Siva Elangovan²

¹Associate Professor, Department of Pathology, KAPV Government Medical College, Tiruchirappalli, Tamil Nadu, India, ²Assistant Professor, Department of Pathology, KAPV Government Medical College, Tiruchirappalli, Tamil Nadu, India

Abstract

Background: Blood and blood products are an inseparable part of treatment in many medical settings. The most important infectious agents that are transmitted via blood transfusion are hepatitis B virus (HBV), hepatitis C virus, HIV, syphilis, and malaria for which there are screening tests performed as a routine in hospitals. The aim of this study was to determine the trend of seroprevalence of hepatitis B infection in voluntary blood donors in our institution.

Materials and Methods: This study was conducted at the blood bank of a tertiary care hospital serving the urban and rural population in and around Tiruchirappalli. A retrospective study on blood donors over a period of 3-year (January 2013-December 2015) was conducted to assess the seroprevalence and the trend of hepatitis B infection in voluntary blood donors in our institution. The second generation enzyme-linked immunosorbent assay was used to detect the antibodies to hepatitis B surface antigen in the donors as a marker of infection.

Results: A total of 27,343 voluntary donors over a period of 3-year were studied. 161 cases were positive with a prevalence of 0.58% which comes under "low prevalence (<2%) zone" as per WHO guidelines. Male donors showed higher seropositivity compared to female donors. Age wise seroprevalence was found to be more in 18-30 years age group.

Conclusion: Tamil Nadu has a low prevalence of hepatitis B in blood donors. Our study showed a decreasing trend in seroprevalence of hepatitis B. This could be due to effective preventive measures as well as improved health-care delivery systems. Our study revealed a high seroprevalence between the age group of 18 and 30 years. Better education of donors and improved prophylactic measures at public level must be done to ensure safe blood donation.

Key words: Blood donors, Infection, Prevalence

INTRODUCTION

Transfusion of blood and blood products as a specialized modality of patient management has been saving many lives. It is well known that there are complications that can occur due to blood transfusion. Some are only trivial and others are life-threatening, demanding for meticulous pre transfusion screening, and testing. The infection that could be transmitted by transfusion of un-screened blood includes

hepatitis B virus (HBV), hepatitis C virus, HIV, syphilis, and malaria, etc. Knowledge of the various infectious agents with special emphasis on the disease endemic in that particular region is essential in understanding the strategies to prevent the transmission of this infection.

Hepatitis B is a major public health problem worldwide. These endogenous microbial agents transmitted by blood transfusion have the following characteristics:

- Long incubation period
- Carrier or latent state
- Ability to cause asymptomatic/sub clinical infection
- Viability and stability in stored blood or plasma
- The hall mark is the persistence of infection.

Approximately, 30% of world's population or about 2 billion persons have serological evidence of either current

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Corresponding Author: Dr. V Bagiyalakshmi, Department of Pathology, KAPV Government Medical College, Tiruchirappalli, Tamil Nadu, India. E-mail: kapvpath@gmail.com

or last infection with HBV.¹ Countries are classified based on endemicity of HBV infection into high (8% or more), intermediate (2-7%) or low (<2%).² Assessment of the quality of donor selection and safety of the blood supply can be estimated by monitoring the prevalence of the serologic markers of infectious disease in screening tests. The prevalence of chronic HBV infection in India ranges from 2% to 10% is shown by different studies.^{1,2} India, therefore, comes under the intermediate to high endemicity category. This infection is transmitted mainly through blood and blood products; vertically from mother to neonates and body secretions.³ Factors such as viral load, in the blood components and immune status of the patient, and may play a role in viral transmission.⁴

Blood transfusion associated hepatitis B viral infection continues to be a major problem in India even after the adoption of mandatory screening of hepatitis B surface antigen (HBsAg) by enzyme-linked immunosorbent assay (ELISA).³ Hepatitis B is caused by a DNA virus which infects the liver. The liver functions are impaired while the virus replicates in the hepatocytes. Hepatitis and liver damage arise as a consequence of immune response to virus in liver cells.⁵ Some blood donors who were negative for surface antigen but positive for the core antibody have been reported to transmit HBV leading to acute hepatitis.⁶ Despite all efforts including the use of a highly sensitive HBsAg test, transmission may still occur from apparently healthy blood donors. This may be attributed to the inability of the screening tests to detect HBsAg during a window period or as a result of the occult HBV infections (OBIs). OBI arises when the HBV DNA is detected, while HBsAg remaining undetectable. In about 20% of cases, the only positive marker is HBV DNA, but in other situations anti-HBs could be detected as well. Several factors may be involved in OBI, including mutated HBsAg, and low-level expression of HBsAg or entrapment of antigen in the circulatory immune complexes.^{7,8}

HBV is present in blood, blood products and body fluid such as vaginal secretions and in low concentration in saliva of active carriers.⁵ The average incubation period of the virus is 90 days from the time of exposure to onset of symptoms but may vary from 6 weeks to 6 months. This study aims to determine, the trends in hepatitis B infection in voluntary blood donors and compare it's prevalence among blood donors from other parts of India.^{9,10}

Aims and Objectives

1. To study the seroprevalence of HBV infection among voluntary blood donors at blood bank MGM Government Hospital attached to KAPV Government Medical College, Tiruchirappalli, Tamil Nadu, India
2. Comparison with similar other studies.

MATERIALS AND METHODS

This study was conducted over a period of 3-year (January 2013-December 2015) at MGM hospital blood bank attached to KAPV Government Medical College, Tiruchirappalli. The study was conducted on voluntary blood donors who came to our blood bank and voluntary blood donation camps in and around Tiruchirappalli. All the blood donors, donating blood in the blood bank were considered as the study population. The family members, friends or relatives of the patients were categorized as replacement donors. People who donate blood without expecting any favor in return or in voluntary blood donation camps were classified as voluntary blood donors. Donors were screened by the standard criteria for donor fitness. They were carefully selected for donation by trained personnel after medical examination and a detailed pre-donation questionnaire form which included the donor register form, information regarding risk factor such as history of surgery, previous illness, hospitalization, and blood transfusion.

Inclusion Criteria

Clinically healthy individuals between 18 and 65 years of age with a body weight of above 45 kg and hemoglobin more than 12.5 g/dl with no significant medical or surgical history were qualified for the donation process.

Exclusion Criteria

Persons belonging to high-risk groups such as patients with chronic diseases, professional blood donors, drug abusers, dialysis patients, pregnant women, patients treated in thalassemia clinics, sexually transmitted disease clinics, and sex workers were excluded from the donation process.

After the blood collection, donor samples were obtained for serological testing. HBsAg screening was done using rapid test kit based on the principle of one step immunoassay. All reactive samples were tested again using the second generation the commercially available Erba Lisa ELISA kit with reported sensitivity of 100% and specificity of 99.9% per the manufacturer's manual. Samples showing repeat test reactivity on both methods were considered positive and were included for calculation of seroprevalence.

RESULTS

A total of 27,343 voluntary blood donors were recorded during our study period (January 2013-December 2015), out of which 25258 were males (92.37%) and 2085 were females (7.6%) (Table 1).

Of the 27,343 cases, 161 cases were found to positive for HBsAg. The prevalence was found to be 0.58%

constituting our area under lower risk group according to WHO guidelines.

Of the 161 cases were found to positive for HBsAg 155 cases were male donors and 6 were female donors, which accounts for prevalence of 0.61% in male donors and 0.29% female donors. Males outnumbered females in HBsAg positivity this could be due to less voluntary blood donation from the females (Table 2).

Our study showed that most of the HBsAg positive cases were in the age group of 18-30 years (74.5%) and the least in more than 50 years (1.2%) (Table 3).

Our study showed an increasing trend of hepatitis B positivity of 24.22% between 2013 and 2014, and a decrease of 6.2% between 2014 and 2015. However, this was not found to be significant as the $P < 1\%$ (Table 4).

DISCUSSION

Provision of safe blood is of paramount importance and its responsibility is solely with the blood transfusion service. Hepatitis B is a major health problem world wise and is associated with life-threatening complications. According to India's Drugs and cosmetics Act (1943), each blood unit has to be tested for hepatitis B infection.²

In our study among 27,343 blood donors screened the overall seroprevalence of HBsAg was observed to be 0.58% (total 161 cases) which is similar to study conducted by Remya *et al.*¹¹ and Gupta *et al.* (2004).¹²

According to the WHO classification Tamil Nadu qualifies as a low prevalence area (<2%) in voluntary blood donors. In comparison with studies conducted in other parts of India the prevalence rate is low² also in comparison with study conducted in Madurai our study showed a lower prevalence rate.²

Transfusion transmitted infection (TTI) Prevalence in India

Place	HBsAg %	Reference
Ludhiana	0.66	Gupta <i>et al.</i> (2004) ⁴
Delhi	2.23	Pahuja <i>et al.</i> (2007) ⁸
Lucknow (Uttar Pradesh)	1.96	Chandre <i>et al.</i> (2009) ¹³
Southern Haryana	1.7	Arora <i>et al.</i> (2010) ¹¹
West Bengal	1.46	Bhattacharya <i>et al.</i> (2007) ¹¹
Bengaluru, Karnataka	1.86	Srikrishna <i>et al.</i> (1999) ¹⁴
Present study	0.58	(2016)

In our study, the seroprevalence of HBsAg was significantly high in male donors (0.61%) as compared to female donors (0.29%), which is similar to that found in a study by Chandrasekhar *et al.* in 2000 at Madurai¹⁵ and Remya *et al.*¹¹

Table 1: Total donors

Year	Male	Female	Total
2013	6560	588	7148
2014	8723	698	9421
2015	9975	799	10,774
Total	25258	2085	27,343

Table 2: Donors positive for HBsAg

Year	Male	Female	Total
2013	31	-	31
2014	65	5	70
2015	59	1	60
Total	155	6	161

HBsAg: Hepatitis B surface antigen

Table 3: Age wise incidence of prevalence of HBsAg

Year	18-30	31-40	41-50	<51	Total
2013	25	06	-	-	31
2014	54	12	4	-	70
2015	41	13	4	2	60
Total	120	31	8	2	161

Table 4: Proportion of hepatitis B positive cases - year wise statistics

Year	Positive	Negative
2013	31	7117
2014	70	9351
2015	60	10,714
Total	161	27,182

In our study majority of sero positive donors were younger than 40 years, and the higher seroprevalence rate was observed in the age group of 18-30 years which is comparable with study conducted by Baba *et al.* in 2000¹⁶ Taseema *et al.* in 2008¹⁷ and Quadri *et al.* in 2013,¹⁸ and Remya *et al.*¹¹

On comparison of the trends of hepatitis B positivity among blood donors in 2013, 2014, and 2015 an increase in positive cases of 24.22% was noted between 2013 and 2014 while in the period of 2014 and 2015 a decrease of 6.2% was seen. However, this change was not found to be significant as value of $P < 1\%$. Rural population with lower literacy rate and a lack of awareness about the disease and its mode of prevention may be the reason for increased incidence. However, screening of blood bank donors for HBsAg does not totally eliminate the risk of HBV infection through blood transfusion. Since, the absence of this marker in the serum does not exclude the presence of HBV infection, who lacked detectable HBsAg but whose exposure to HBV infection was indicated by a

positive anti-HBc and HBV DNA, are a potential sources of HBV infection.⁴

Higher seroprevalence in youth in our study needs further re-intensification of preventive programs aimed at high-risk behavioral change, as this is the most productive and economically viable group of the population. Ensuring the safety of patients by reducing the residual risk of transfusion-transmitted hepatitis is the concern of every transfusion center. The introduction of 3rd generation sensitive test has reduced the incidence of post transfusion hepatitis B. However, the risk has not been eliminated. The risk of infection is higher in pooled plasma products. The risk of transmission of HBV can further be reduced by screening the blood donations for anti-HBC, as it is the only marker of HBV during the window period. Active HBV vaccination is another approach to reduce the rate of transmission of HBV. Public awareness, educational, and motivational programs, mass immunization programs ensuring 100% voluntary blood donation, implementation of strict pre-donation counseling, and donor selection criteria will be effective in decreasing the hepatitis B infection rate.

CONCLUSION

The low seroprevalence rate in our study, further recommends comprehensive screening of blood donors. With the advent of nucleic acid amplification techniques, western countries have decreased the risk of TTI to a major extent. However, the cost effectiveness is poor. NAT has added benefits but its high financial cost of concern. Since, our study revealed a high seroprevalence between the age group of 18-30, better education of donors and improved prophylactic measures at public level must be done to ensure safe blood donation. Immunization being the most effective and economic means of prevention along with education of high-risk group and health-care personnel reduce the risk of transmission. Proper pre-donation counseling and donor self-exclusion and 100% voluntary blood donation are some of the effective control measures.

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