Original Research Article

Seroprevalence of Australia antigen (HbsAg) among blood donors in local population

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Abstract

Introduction: Transfusion of Blood & Blood Components is one of the four recognized modes of Hepatitis B virus infection and HBsAg or Australia Antigen in the serum is the earliest marker of active HBV infection (acute/chronic) being detectable even before elimination of transaminases and onset of clinical illness. Various strategies are being used to reduce this transfusion transmitted infection. **Objectives:** To determine the Seroprevalence of HBsAg among blood donors in and around Junagadh (Gujarat) and to compare it withthat of other regions in India. **Methods:** The study was conducted on apparently healthy blood donors over a period of 3 years from January-2015 to December-2017 at Blood Bank, Department of Pathology, GMERS Medical College and Hospital, Junagadh in order to assess the prevalence of hepatitis B virus infection. A total number of 18368 blood donors were included in this study. Both rapid HBsAg card test and HBsAg ELISA test were used for this study purpose. **Result:** Out of 18368 donors, 14102 (76.77%) were in-house donors and 4266 (23.23%) were outdoor-camp donors. 17346 (94.44%) were males & 1022 (5.56%) were females. Out of 18368 blood units, 487 (2.65%) were discarded and out of them 109 (22.38%) were HBsAg reactive. The Seroprevalence of HBsAg was found to be 0.59%. **Conclusion:** Blood Donors are often found to be reactive for Australia Antigen and others. In order to reduce this Seroprevalence, more sensitive screening assays and appropriate donor selection are must.

Key words: Seroprevalence, Australia Antigen, Hepatitis B surface antigen

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Introduction

Hepatitis B infection has become an issue of global importance. Hepatitis B causes an estimated 1-2 million deaths per year worldwide [1, 2] and it is estimated that there are 300 million carriers of Hepatitis B virus in the world. Countries are classified on the basis of endemicity of Hepatitis B virus infection into high (8% or more, e.g. equatorial Africa, South East Asia, China, parts of South America), intermediate (2-7%, e.g. Eastern Europe, Middle East, South Asia) or low (<2%, e.g. developed countries as North America and Australia) incidence countries [1]. The prevalence of chronic hepatitis B infection in India ranges from 2-10% as shown by different studies [2]. Transfusion associated hepatitis B viral infection (TAHBV) continues to be a major problem in India even after adoption of mandatory screening of hepatitis B surface antigen (HBsAg) by enzyme-linked immuno-sorbent assay (ELISA).

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The high incidence of TAHBV is reported in patients receiving multiple blood transfusions. This infection is the leading cause of morbidity and mortality not only because of the acute illness but also due to its chronic sequel like chronic hepatitis, cirrhosis and Hepatocellular carcinoma. Therefore we evaluated the seroprevalence of hepatitis B virus among blood donors. Hepatitis B is a major public health problem worldwide.

These endogenous microbial agents transmitted by bloodtransfusion 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.

Currently there are four recognized modes of hepatitis B infection – mother to child at birth (perinatal), contact with infected person(horizontal), sexual contact and parenteral route through blood/fluids. HBsAg in the serum is the earliest marker of active HBV infection (acute/chronic) being detectable even before elimination of transaminases and onset of clinical illness.

The strategies used to reduce the transfusion transmitted infections includes improving donor selection, testing the donated blood for specific antibodies against infectious agents, using autologous transfusion [3,4] but the transmission of disease still occurs [5] because of the inability to detect the disease in window phase of the infection, prevalence of asymptomatic carriers, false negative results, immunologically variant viruses and laboratory testing errors [6]. To understand and assess the magnitude and dynamics of transmission of a disease in a community and for its control and prevention and prevention control and prevention, the assessment and study of its prevalence is very important.

The samples were obtained for serological testing. HbsAg screening was done using rapid test kit based on the principle of a one-step immunoassay (Hepa-Card and Meril, India) and Erbalisa, Merilisa and Microscreen for qualitative detection (screening) of HBsAg in serum/plasma.Samples showing repeat test reactivity on both methods were considered positive and were included for calculation of seroprevalence.

Materials & Methods

Place of the study: Blood Bank, Department of Pathology, GMERS Medical College & Hospital, Junagadh, Gujarat (India)
Type of the study: Retrospective

Sampling Methods: Relevant data has been collected from previous blood bank records and includes a total number of 18368 blood donors both In-house & Outdoor-camp. Duration of the study is 3 years from January 2015 to December 2017.

Donors were carefully selected for donation after satisfactorily answering the donors' questionnaire and passing the physical examination conducted by the physician-in charge.

All the collected blood units were screened for Hepatitis B surface antigen or Australia Antigen using two different testing methods namely (1) Rapid HBsAg card test (Hepa-Card and Meril) and (2) HBsAg ELISA test (Erbalisa, Merilisa and Microscreen) for qualitative detection (screening) of HBsAg in serum/plasma.

All the tests were performed according to the manufacturer's instructions with adequate controls.

Inclusion Criteria: Clinically and Apparently healthy individuals between 18 and 65 years of age and having body weight more than45kg & Hemoglobin level more than 12.5 g/dl with no significant history of any medical or surgical illness 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 ladies, patients treated in Thalassemia clinics, patients treated in Sexually Transmitted Disease clinics and sex workers were excluded from the process of blood donation and also from this present study.

Results

A total number of 18368 blood donors were screened over a period of 3 years from January 2015 to December 2017. Out of them, 14102 (76.77%) were in-house donors and 4266 (23.23%) were outdoor-camp donors. Out of 18368 donors 17346(94.44%) were male donors and 1022(05.56%) were female donors. Table no. 1 shows year wise percentage of Outdoor-camp donors and In-house donors. Table no. 2 shows year wise percentage of Male donors and Female donors.

Table No.-1: Trends in Outdoor-camp and In-house blood donation (Year-wise)

Year	Total No. of Donors	No. of In-House Donors	Percentage of In-House Donors	No. of Outdoor-camp Donors	Percentage of Outdoor-camp Donors
2015	6609	5108	77.29	1501	22.71
2016	5494	4140	75.35	1354	24.65
2017	6265	4854	77.48	1411	22.52
Total	**18368**	**14102**	**76.77**	**4266**	**23.23**

Table No.-2: Trends in Male & Female blood donation (Year-wise)

Year	Total No. of Donors	No. of Male Donors	Percentage of MaleDonors	No. of Female Donors	Percentage of Female Donors
2015	6609	6229	94.25	380	5.75
2016	5494	5206	94.76	288	5.24
2017	6265	5911	94.35	354	5.65
Total	**18368**	**17346**	**94.45**	**1022**	**5.55**

Out of 18368 blood units collected, 487 (2.65%) units were discarded and out of them, 109 (22.38%) units were HBsAg Reactive. The prevalence of Seropositivity for HBsAg was found to be 0.59%.

Table-3: Incidence of HBsAg among donors during 2015-2017

Year	Total No. of Donors	Total No. of Bags Discarded	Percentage of Bags Discarded	Total No. of HBsAg Reactive Units	Percentage of HBsAg Reactive Units
2015	6609	189	2.86	40	0.61
2016	5494	202	3.68	42	0.76
2017	6265	96	1.53	27	0.43
Total	**18368**	**487**	**2.65**	**109**	**0.59**

Table-4: Percentage of Blood units discarded due to HBsAg Reactivity during 2015-2017

Year	Total No. of Bags Discarded	Total No. of HBsAg Reactive Units	Percentage of Blood units discarded due to HBsAg Reactivity
2015	189	40	21.16
2016	202	42	20.79
2017	96	27	28.13
Total	**487**	**109**	**22.38**

Table no. 3 shows year wise percentages of Discarded Blood Units and HBsAg reactive Units. Table no. 4 shows Percentage of Blood units discarded due to HBsAg Reactivity during 2015-2017.

Discussion

Hepatitis B is one of the most common transfusion transmissible infections. The prevalence of this infection varies across the different geographical regions. Noting the trend of seroprevalence of hepatitis B is useful to assist the preventive strategies. The aim of this study was to determine the trend of seroprevalence of hepatitis B in Bijapur District, Karnataka over a period of two years six monthsHepatitis B is one of the most common transfusion transmissible infections. The prevalence of this infection varies across the different geographical regions. Noting the trend of seroprevalence of hepatitis B is useful to assist the preventive strategies. The aim of this study was to determine the trend of seroprevalence of hepatitis B in Bijapur District, Karnataka over a period of two years six monthsHepatitis B is one of the most common transfusion transmissible infections. The prevalence of this infection varies across the different geographical regions. Noting the trend of seroprevalence of hepatitis B is useful to assist the preventive strategies. The aim of this study was to determine the trend of seroprevalence of hepatitis B in Bijapur District, Karnataka over a period of two years six monthsHepatitis B is one of the most common transfusion transmissible infections.The prevalence of this infection varies across the different geographical regions. Noting the trend of seroprevalence of hepatitis B is useful to assist the preventive strategies.The aim of this study was to determine the trend of seroprevalence of Hepatitis B in Junagadh District, Gujarat over a period of three years.

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 [7]. According to India’s Drugs and Cosmetics Act (1945), each blood unit has to be tested for hepatitis B virus infection (Drugs and Cosmetics Act 1940). About 5% (300 millions), of world population has chronic infection HBV, which is major factor for developing of chronic liver cirrhosis and hepatocellular carcinoma.

Table-5: Comparison of Seroprevalence of HBsAg among Blood Donors in different other studies

Name of Study	Year	Place	Seroprevalence
Srikrishna et al [8]	1999	Bangalore	1.86%
Chhattoraj et al [9]	2008	Pune	0.99%
Karandeepsinh et al [10]	2009	Costal Karnataka	0.62%
Gagandeep Kaur et al [11]	2010	Chandigarh	0.65%
S Gulia et al [12]	2011	Vizianagaram	2.48%
Poojaba Jadeja et al [13]	2011	Udaipur, Rajasthan	1.32%
Present study	2018	Junagadh, Gujarat	**0.59%**

Among the 18368 screened samples, 109 of them (0.59%) were found positive for HBsAg. Similar type of results was found in an Indian study during the year 2008 [17] and year 2015 [18]. In contrast, seropositivity in another study was observed to be as low as 1.55% in 1996 and 0.99% in2002 [19]. A community cluster survey on STD prevalence conducted in Tamil Nadu showed an HBsAg prevalence rate of about 5.7% [20].

In our study, the overall Seroprevalence of HBsAg was observed to be 0.59%. According to the WHO classification, this part of the Gujarat qualifies as a low prevalence area (less than 2%). The data providing a picture of hepatitis B infection burden in India has come from HBsAg Seroprevalence studies (Table 5). Comparison with the other parts of India, the present study shows low Seroprevalence of hepatitis B infection in Gujarat.

If we compare the HBsAg positive in other developing countries of the world the rate is quite high as compared to India. Table 6 shows prevalence of HBsAg in other countries [14,15,16].

Table-6: Prevalence of HBsAg in other countries

Name of the Country	Percentage of HBsAg Seropositivity
Egypt	39.4
Indonesia	8.8
Ghana	15.0
Nepal	2.5

Table 7 shows the burden of hepatitis B in rest of India as found by the sero-prevalence studies. In comparison with the other parts of India, our study shows seroprevalence of hepatitis B infection in Gujaratregion.

Table-7: Prevalence of HBsAg positive donors indifferent states of India [21, 22, 23, 24, 25].

Place	Prevalence
New Delhi	2.23%, 2.76%
Kerala	3.1%
Mudarai	4%
Tamilnadu - Voluntary - Replacement	 1.37% 2.96%
Dehradun	0.99%
Kolkata	1.66%
Kanpur	2.25%
Bangalore	1.86%
Kasmir	0.35%

This variation in the prevalence of hepatitis B infection in different countries depends upon a mix of behavioral, environmental and host factors, incidence and age of primary infection. It is lowest in areas with high standards of living and highest in areas with low socioeconomic levels.

On comparison of the trends of hepatitis B positive among blood donors in 2015, 2016, and 2017. Positive cases of 0.61% 2015, in 20160.76% and in 2017 0.43% was noted. 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 [26].

Conclusion

Blood donors represent apparently healthy population of a particular geographical region. Occasionally out of them, some people are found to be reactive for Australia Antigen and many other similar antigens as well as antibodies. So to reduce Seroprevalence of HBsAg, more sensitive screening assays and proper donor selection are must. Ensuring the safety of patients by reducing the residual risk of transfusion transmitted hepatitis is the concern of every transfusion center. Reduction in seroprevalence among voluntary donors requires an effective donor education and high quality selection programme especially during big blood donation camps. Along with advanced technology for donor screening and other factors such as public awareness, educational and motivational programs, and mass immunization programs help in decreasing the infection. Pre-donation counseling, donor self-exclusion and ensuring 100% voluntary blood donation will be effective in decreasing the hepatitis B infection rate. This study provides a helpful guide in reducing the residual risk of transfusion-transmitted hepatitis not only in India, but also in the other developing countries of the world. To conclude, with the implementation of strict selection criteria of donor as per the guidelines laiddown for blood banks in the gazette notification by the Government of India and use of sensitive laboratoryscreening tests, it is possible to decrease the incidence of seropositivity of transfusion-transmitted infectionsandimprove the blood product safety.

Contribution from the Author

- **Dr. Mayur J. Kokani:** Data collection, analysis and preparation of manuscript.
- **Dr. Chiragkumar B. Menapara:** Analysis and preparation of manuscript & critical revision.

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