

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

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## Abstract

**Introduction:** Hepatitis B virus (HBV) causes silent killer disease of the liver with many carriers not aware of their clinical status, therefore, they act as potential source of infection to others. HBV is highly infectious and can be transmitted by both percutaneous routes and by blood transfusion. Laboratory diagnosis of HBV infection is made by detecting Hepatitis B virus surface antigen (HBsAg), the earliest serological marker of active HBV infection (acute as well as chronic). **Objectives:** To determine the Seroprevalence of HBsAg among blood donors in and around Valsad district (Gujarat) and to compare it with that of other regions in India. **Methods:** The study was conducted on apparently healthy blood donors over a period of 3 years from January-2016 to December-2018 at Blood Bank, Department of Pathology, GMERS Medical College and Hospital, Valsad in order to assess the prevalence of hepatitis B virus infection. A total number of 4947 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 4947 donors, 4551 (91.99%) were males & 396 (8.00%) were females. Out of blood units, 222 (4.48%) were discarded and out of them 55 (1.11%) were HBsAg reactive. The Seroprevalence of HBsAg was found to be 1.11%. **Conclusion:** Blood Donors are often found to be reactive for hepatitis B surface antigen and others. In order to reduce this Seroprevalence, more sensitive screening assays and appropriate donor selection are must.

**Keywords:** Seroprevalence, Hepatitis B surface antigen, Blood donors

## Introduction

Hepatitis B virus (HBV) infection is a serious global health problem affecting 2 billion people worldwide [1]. HBV infection accounts for 5,00,000 to 1.2 million deaths each year and is the 10th leading cause of death [2]. HBV is one of the major causes of chronic liver disease with around 350 million people suffering from chronic HBV infection such as chronic hepatitis, cirrhosis and hepatocellular carcinoma (HCC) [3]. The prevalence of HBV infection varies markedly in different geographic areas of 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 [4]. The prevalence of chronic hepatitis B infection in India ranges from 2-10% as shown by different studies [5]. 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).

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

HBV is present in blood, blood products and body fluid such as vaginal secretions and in low concentration in saliva of active carriers [6]. 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.

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This study's important to determine, the seroprevalence of hepatitis B infection in blood donors in and around Valsad districts and compare its prevalence among blood donors from other parts of India [7,8].

## Materials and Methods

The study was conducted at the blood bank of GMERS medical college and hospital, Valsad. In this retrospective study, the present study reviewed 4947 healthy blood donors over a period of 3 years from January 2016 to December 2018.

The study was approved by the Institutional Ethical Committee. An informed consent was taken from all blood donors included in the study prior to sample collection. They were carefully selected for blood donation by trained personnel after a complete physical examination and satisfactorily answering the donor's questionnaire.

### 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.

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

All the tests were performed according to the manufacturer's instructions with adequate controls. Data regarding the HbsAg positivity and negativity of the respective blood donor were taken from records available in the blood bank of GMERS medical college and hospital, Valsad.

## Results

A total number of 4947 blood donors were screened over a period of 3 years from January 2016 to December 2018. Out of 4947 donors, 4551 (91.99%) were male donors and 396 (8.00%) were female donors. Table no. 1 shows year wise percentage of Male donors and Female donors.

**Table No.-1: Trends in Male & Female blood donation (Year-wise)**

Year	Total No. of Donors	No. of Male Donors	Percentage of Male Donors	No. of Female Donors	Percentage of Female Donors
2016	1976	1804	91.29	172	8.70
2017	1650	1496	90.66	154	9.33
2018	1321	1251	94.70	70	5.29
<b>Total</b>	<b>4947</b>	<b>4551</b>	<b>91.99</b>	<b>396</b>	<b>8.00</b>

**Table-2: Incidence of HBsAg among donors during 2016-2018**

Year	Total No. of Donors	Total No. of HBsAg Reactive Units	Percentage of HBsAg Reactive Units
2016	1976	16	0.80
2017	1650	16	0.96
2018	1321	23	1.74
<b>Total</b>	<b>4947</b>	<b>55</b>	<b>1.11</b>

Table 2 signifies year wise distribution from 2016-2018 about the trends in the total number of HBsAg Reactive Units.

**Table-3: Percentage of Blood units discarded due to HBsAg Reactivity during 2016-2018**

Year	Total No. of donors	Total No. of Bags Discarded	Percentage of bag discarded	Total No. of HBsAg Reactive Units	Percentage of HBsAg Reactive Units
2016	1976	63	3.18	16	0.80
2017	1650	99	6.00	16	0.96
2018	1321	60	4.54	23	1.74
<b>Total</b>	<b>4947</b>	<b>222</b>	<b>4.48</b>	<b>55</b>	<b>1.11</b>

Table 3 represented year wise distribution from 2016-2018 about the trends in the total number Blood units discarded due to HBsAg Reactivity.

## Discussion

The discovery of the HBsAg was a major breakthrough in decreasing the incidence of post transfusion hepatitis. Following infection by the hepatitis B virus (HBV), the first serological marker to appear in the blood is the HBV DNA, followed by HBsAg, the DNA polymerase and the hepatitis B 'e' antigen (HBeAg). Thereafter, the antibodies to the hepatitis B core antigen (anti-HBc), hepatitis B 'e' antigen and the HBsAg can be detected. Screening of donated blood by ELISA for HBsAg is the common method for detecting hepatitis B infection. Screening of blood for the detection of this viral marker, however, does not rule out the risk of transmission of hepatitis B totally, because during the host serological response to infection, there is a phase during which the HBsAg cannot be detected in the blood, although, hepatitis B infection is present. This phase is called the 'window period'. It represents a carrier state of the disease. Therefore, a definite hazard of transmission of hepatitis B to recipients of such units of donated blood exists. During this 'window period', detection of the anti-HBc serves as a useful serological marker for hepatitis B infection. The IgM class of the anti-HBc is the first to appear and indicates a recent infection.

The IgG variety of anti-HBc appears later during the infection and points to a past HBV infection. Individuals with IgG variety of anti-HBc may not be infectious as they may have sufficiently high titres of antibodies to HBsAg (anti-HBs), which are protective in nature and the affected individuals may actually be disease free. With the fairly high incidence of HBsAg in India, there is a definite risk of inadvertently transfusing HBV infected blood. It is therefore strongly felt that a marker must be utilized for the screening of blood in the Indian population to detect the presence of hepatitis B during the window period. The safety of blood products is one of the major problems concerned with the transfusion medicine. At present, HBsAg detection is the only diagnostic screening test for HBV infection identification in the blood transfusion centers of India. The prevalence of anti-HBc in the sera of healthy blood donors negative for HBsAg was not much considered. Since anti-HBc detection is not mandatory in India, the present study was aimed to evaluate if anti-HBc could be adopted as an additional screening assay for blood donation.

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). Hepatitis B virus infection can be estimated by detection of HBsAg in sera. Hence, the present study was done to detect prevalence of HBV in our local area by screening blood of blood donors attending our hospital.

**Table-4: Comparison of Seroprevalence of HBsAg among Blood Donors in different other studies.**

Name of Study	Year	Place	Seroprevalence
Srikrishna et al [9]	1999	Bangalore	1.86%
Chhattoraj et al [10]	2008	Pune	0.99%
Karandeepsinh et al [11]	2009	Costal Karnataka	0.62%
Gagandeep Kaur et al [12]	2010	Chandigarh	0.65%
S Gulia et al [13]	2011	Vizianagaram	2.48%
Poojaba Jadeja et al [14]	2011	Udaipur, Rajasthan	1.32%
Present study	2019	Valsad, Gujarat	1.11%

Among the 4947 screened samples, 55 of them (1.11%) were found positive for HBsAg. Similar type of results was found in an Indian study during the year 1999 [9] and year 2011[14]. In contrast, seropositivity in another study was observed to be as low as 1.55% in 1996 and 0.99% in 2002 [15]. A community cluster survey on STD prevalence conducted in Tamil Nadu showed an HBsAg prevalence rate of about 5.7% [16].

In the present study, the overall Seroprevalence of HBsAg was observed to be 1.11%. 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 4). Comparison with the other parts of India, the present study shows low Seroprevalence of hepatitis B infection in Gujarat.

Table 5 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, the present study shows seroprevalence of hepatitis B infection in Gujarat region.

**Table-5: Prevalence of HBsAg positive donors' indifferent states of India [17,18,19,20,21]**

Place	Prevalence
New Delhi	2.23%, 2.76%
Kerala	3.1%
Mudarai	4%
Tamil Nadu	
- Voluntary	1.37%
- Replacement	2.96%
Dehradun	0.99%
Kolkata	1.66%
Kanpur	2.25%
Bangalore	1.86%
Kashmir	0.35%
Present Study	1.11%

The comparison between 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 [22,23].

**Table-6: Prevalence of HBsAg in other countries**

Name of the Country	Percentage of HBsAg Seropositivity
Egypt	39.4
Indonesia	18.8
Ghana	15.0
Nepal	2.5

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 2016, 2017 and 2018. Positive cases of 0.80% 2016, in 2017, 0.96% and in 2018, 1.74% 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. The introduction of 4rd 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 counselling, and donor selection criteria will be effective in decreasing the hepatitis B infection rate.

## 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 center.

Reduction in seroprevalence among voluntary donors requires an effective donor education and high-quality selection program 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 guide in reducing the residual risk of transfusion transmitted hepatitis not only in India, but also in the other developing countries of the world.

## What the study adds to the existing knowledge?

With the implementation of strict selection criteria of donor as per the guidelines laid down for blood banks in the gazette notification by the Government of India and use of sensitive laboratory screening tests, it is possible to decrease the incidence of seropositivity of transfusion-transmitted infections and improve the blood product safety.

## Author's contribution

**Dr. Kamini Patel:** Data collection, analysis and preparation of manuscript.

**Dr. Sunita Mistry, Dr. Kamlesh Shah and Dr. Niraj Patel:** Analysis and preparation of manuscript & critical revision.

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