

## Seroprevalence of Hepatitis B virus among blood donors at a tertiary care hospital in Gujarat

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### Abstract

**Introduction:** Transfusion of blood and blood components, as a specialized modality of patient management saves millions of lives worldwide each year and reduces morbidity. Transfusion-transmitted infectious (TTIs) diseases remain a major topic of interest for those involved in blood safety. Screening of TTIs among blood donors is helpful to observe the seroprevalence of HBV among healthy blood donors.

**Materials and Methods:** A cross-sectional study based on observance of records was conducted at Blood Bank of tertiary care hospital in Gujarat. Total 7,935 donors were screened over the period of year 2010 to 2017 according to the guideline of WHO.

**Results:** Blood units were collected from replacement donors (54.1%) and voluntary blood donors (45.9%). Male donors (97.4%) outnumbered female donors. Seroprevalence for HBV was found to be 0.98%.

**Conclusion:** Replacement donors were higher in number than the voluntary donors. Stringent measures need to be taken on urgent basis including dissemination of information, mandatory screening protocol of blood and blood products with test having sensitivity and specificity, better donor recruitment, advocacy of voluntary donation, proper sterilization of instruments, proper disposal of contaminated material, and immunization of people at risk, particularly health care workers.

**Keywords:** Blood Donors, HBV, Replacement Donors, Seroprevalence, Transfusion Transmitted Infection (TTIs), Voluntary Donors.

### Introduction

Blood donation is a process involving the collection, testing, preparing, and storing of blood and blood components. A voluntary blood donor is a person who donates blood voluntarily for a sense of community responsibility and does not receive payment. A replacement donor, either a friend or family member of the recipient, is someone who donates blood to replace the blood that is used for a transfusion, to ensure a consistent supply. Transfusion of blood and blood components, as a specialized modality of patient management saves millions of lives worldwide each year and reduces morbidity.<sup>1</sup> Transfusion-transmitted infectious (TTIs) diseases remain a major topic of interest for those involved in blood safety.<sup>2</sup>

The risk of transfusion-transmitted infection with pathogenic blood-borne viruses such as hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus type 1 (HIV-1) has been reduced by improving donor selection and by the development of sensitive serological tests to screen for HBV surface antigen (HBsAg) and antibodies to HCV and HIV-1.<sup>3</sup> However, a residual risk of viral infection persists related to the pre-seroconversion window period, infection with immunovariant viruses, immunosilent carriage, or occult carriage in the case of HBV infection.<sup>4</sup>

Hepatitis B virus infection is a serious global health problem affecting 2 billion people world-wide and 350 million people suffer from chronic HBV infection.<sup>5</sup> Countries are classified on the basis of endemicity of HBV infection into high ( $\geq 8\%$ ), intermediate (2 to 7%) or low ( $\leq 2\%$ ) incidence countries.<sup>6</sup> The prevalence of

chronic HBV infection in India ranges from 2 to 10%. India therefore comes under the intermediate to high endemicity category.<sup>7</sup> HBV is highly infectious and can be transmitted covertly by percutaneous routes and overtly by blood transfusion. HBV infection is the leading cause of chronic hepatitis, cirrhosis, and hepatocellular carcinoma.<sup>8</sup>

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 immunosorbent assay (ELISA).<sup>1</sup> The high incidence of TAHBV is reported in patients receiving multiple blood transfusions.<sup>1</sup> Factors such as blood donations during the window period, emergence of newer transmissible pathogens, and prevalence of asymptomatic carriers pose a serious challenge to blood safety. Hence, constant monitoring and retrospective analysis of the incidence of TTIs, notably HBV among voluntary as well as replacement blood donors becomes essential to evaluate the prevalence of TTIs in the population. The present study was conducted to understand the seroprevalence of HBV among blood donors of a tertiary care hospital in Gujarat State over a period of 7 years.

### Materials and Methods

This descriptive cross-sectional study was conducted at Blood Bank of GMERS Medical College and Civil Hospital, Himmatnagar, Gujarat, India. Blood bank records over a period of seven years from January 2010 to December 2017 were reviewed, retrospectively, after ethical permission of Institutional Ethical Committee.

Records from both replacement donors as well as voluntary donors were included in the study. Precaution was taken to exclude professional donors by taking relevant history and examination.

We included seven consecutive years in our study to identify the trend of increase or decrease the incidence of TTIs. Tests are routinely done on every blood unit to exclude HBV infection. During this period 7,935 donors were tested. Blood was collected from healthy donors as criteria set by WHO.<sup>9</sup>

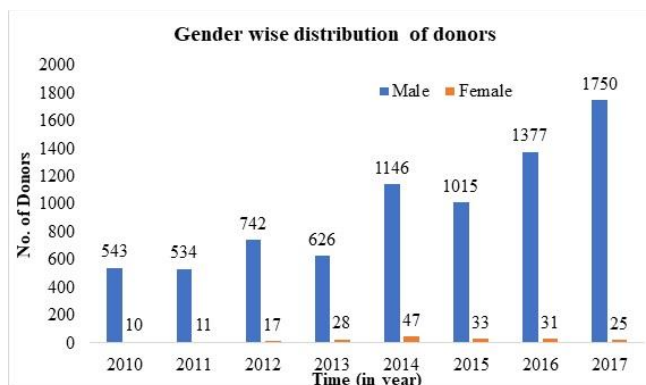
Standardized kits were used for detection of HBV, namely, Genscreen ULTRA enzyme-linked immunosorbent assay (ELISA) kit (Bio-Rad, Marnes-la-Coquette, France) or bioMérieux ELISA kit (Helsinki, Finland), based on the hepatitis B surface antigen (HBsAg) detection. All the donors who turned out to be reactive for HBsAg were confirmed by doing a repeat test followed by a confirmatory test before labeling the sample as HBsAg positive. The blood that was still seropositive was discarded.

**Results**

**Table 1: Gender wise distribution of donors (N=7935)**

| Year  | Total Donors | Replacement Donors (%) |          | Voluntary Donors (%) |           |
|-------|--------------|------------------------|----------|----------------------|-----------|
|       |              | Male                   | Female   | Male                 | Female    |
| 2010  | 553 (7.0)    | 336 (7.9)              | 2 (5.6)  | 207 (5.9)            | 8 (4.8)   |
| 2011  | 545 (6.9)    | 326 (7.7)              | 4 (11.1) | 208 (6.0)            | 7 (4.2)   |
| 2012  | 759 (9.6)    | 380 (8.9)              | 3 (8.3)  | 362 (10.4)           | 14 (8.4)  |
| 2013  | 654 (8.2)    | 242 (5.7)              | 0 (0.0)  | 384 (11.0)           | 28 (16.9) |
| 2014  | 1193 (15.0)  | 488 (11.5)             | 2 (5.6)  | 658 (18.9)           | 45 (27.1) |
| 2015  | 1048 (13.2)  | 650 (15.3)             | 4 (11.1) | 365 (10.5)           | 29 (17.5) |
| 2016  | 1408 (17.7)  | 764 (18.0)             | 12(33.3) | 613 (17.6)           | 19 (11.4) |
| 2017  | 1775 (22.4)  | 1065 (25.1)            | 9 (25.0) | 685 (19.7)           | 16 (9.6)  |
| Total | 7935 (100.0) | 4251 (53.6)            | 36 (0.5) | 3482 (43.9)          | 166 (2.1) |

Table 1 and Fig. 1 shows that total 7935 blood units were collected from replacement donors (54.1%) and voluntary blood donors (45.9%) at the study setting during January 2010 to December 2017. Highest number (25.1%) of blood donors noted during year 2017 and lowest (7.9%) in 2010. Out of total blood donors, 97.4% were male and remaining were female.



**Fig. 1: Gender wise distribution of donors (N=7935)**

**Table 2: Year wise distribution of HBV seropositive donors (N=7935)**

| Year | Total Blood donors | Total HBV Seropositive (%) |
|------|--------------------|----------------------------|
| 2010 | 553                | 7 (1.3)                    |
| 2011 | 545                | 4 (0.7)                    |
| 2012 | 759                | 9 (1.2)                    |
| 2013 | 654                | 12 (1.9)                   |
| 2014 | 1193               | 12 (1.0)                   |
| 2015 | 1048               | 12 (1.1)                   |
| 2016 | 1408               | 13 (0.9)                   |

|       |      |           |
|-------|------|-----------|
| 2017  | 1775 | 9 (0.5)   |
| Total | 7935 | 78 (0.98) |

Table 2 shows that 0.98% blood donors were found seropositive for HBV. Highest incidence of HBV seropositive was found in year 2013.

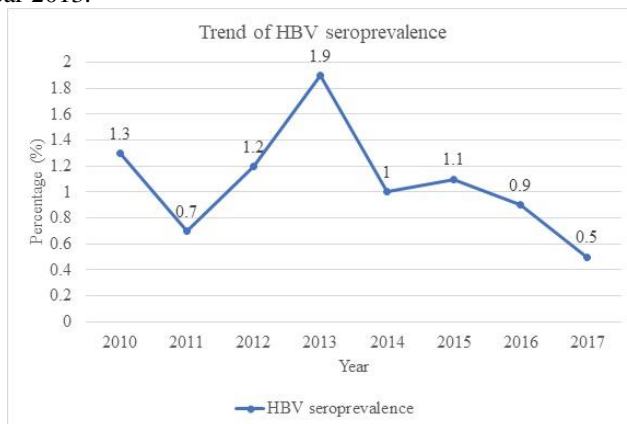


Fig. 2: Trend of seroprevalence of HBV among blood donors (N=7935)

**Discussion**

Blood transfusion services are an integral part of health care system, which potentially saves lots of lives every day. Blood and blood products must be free from HIV, hepatitis viruses and other threatening infections and transfused safely to the needy persons which is the basic requirement of each country of the world. According to World Health Organization (WHO) guideline, at minimum, all the blood and blood products for transfusion should be tested for HIV, Hepatitis B & C and Syphilis.<sup>10</sup>

Replacement donation is encouraged by WHO. In present study, 45.9% were voluntary and 54.1% were replacement donors. This finding is comparable with the study from Karnataka<sup>11</sup> and from Haryana<sup>12</sup> which reported proportion of voluntary donors as 58% and 31.4% respectively. However, studies done by Sehgal S et al<sup>10</sup> and Patel PA et al<sup>13</sup> from western Ahmedabad reported voluntary blood donors as 77.6% & 95.56% respectively.

In our study, males (97.6%) outnumbered females (2.4%). This finding agrees with similar other studies

done in India by Shehgal S et al,<sup>10</sup> Pallavi P et al,<sup>14</sup> Patel PA et al,<sup>13</sup> Arora D et al,<sup>12</sup> Singh K et al<sup>15</sup> and Pahuja et al,<sup>16</sup> all of which observed more than 90% of the male donors.

The World Health Organization recommends that to minimize the risk of HBV infection through the route of transfusion, screening should be performed using a highly sensitive and specific HBsAg immunoassay, that is, enzyme immunoassay or chemiluminescent immunoassay. Screening using a highly sensitive and specific HBsAg rapid assay or particle agglutination assay may be performed in laboratories with small throughput or in emergency situations.<sup>17</sup>

HBV is one of the major global public health problems. India lies in an intermediate HBV endemicity zone and the number of HBV carriers is estimated to be 50 million, forming the second largest global pool of chronic HBV infections.<sup>18</sup> HBV prevalence in general population in India is 2% to 8% and 0.5% to 3% in the blood donors, according to various studies as depicted in Table 3.

Table 3: Comparison HBV seropositive prevalence of various studies with present study

| Study  | HBV Seropositivity (%) |
|--|------------------------|
| Garg et al 2001, Rajasthan <sup>19</sup>       | 3.44                   |
| Gupta et al 2004, Ludhiana <sup>20</sup>       | 0.66                   |
| Bhattacharya et al 2007, Kolkata <sup>21</sup> | 1.46                   |
| Panda & Kar 2008, Orissa <sup>22</sup>         | 1.13                   |
| Chandra et al 2009, Lucknow <sup>23</sup>      | 1.96                   |
| Arora D et al 2010, Hariyana <sup>12</sup>     | 1.7                    |
| Das BK et al 2011, Kolkata <sup>24</sup>       | 1.5                    |
| Meena et al 2011, Delhi <sup>25</sup>          | 1.43                   |
| Pallavi P et al 2011, Mysore <sup>14</sup>     | 1.27                   |

|  |      |
|--|------|
| Kulkarni N et al 2012, Karnataka <sup>11</sup> | 3.2  |
| Shah N et al 2013, Ahmedabad <sup>26</sup>     | 0.97 |
| Pathak S et al 2013, Delhi <sup>27</sup>       | 0.2  |
| Bodariya et al 2013, Gujarat <sup>28</sup>     | 0.6  |
| Present study                                  | 0.98 |

## Conclusion

Present study shows that replacement donors were higher in number than the voluntary donors. Blood camps should be increased to encourage the people for voluntary blood donation, particularly in a developing country like India where availability of safe blood and blood components for transfusion is main challenge.

Considering the vast population of the country, even low prevalence amounts to large number of infected people. A prevalence of even 1% leads to millions of seropositive patients. Stringent measures need to be taken on urgent basis including dissemination of information, mandatory screening protocol of blood and blood products with test having sensitivity and specificity, better donor recruitment, proper sterilization of instruments, proper disposal of contaminated material, and immunization of people at risk, particularly health care workers.

## Limitation

The present study is based on the blood bank records of past several years. As blood donors are specifically selected based on extensive questionnaire and a physical examination at a tertiary care hospital, apparently only healthy individuals with lowest risk of TTIs are allowed to donate blood. Further, the donor pool was predominantly composed of male population and with only 2.4% of female donors, the prevalence cannot be generalized to female population of this region.

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**Conflict of interest:** None declared.

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