Seroprevalence and trend of Hepatitis B virus infection among the blood donors of North Karnataka: A Nine Year Study

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Abstract

Introduction: Hepatitis B is one of the leading transfusion transmissible infections. The prevalence of this infection varies across the different geographical areas with intermediate prevalence in India. Studying the trend in seroprevalence is useful to assist the preventive strategies. The aim of this study was to determine the trend of seroprevalence of hepatitis B in North Karnataka region over a nine-year period (2007-2015). Materials & Methodology: The study was conducted at one of the largest blood banks of Northern Karnataka of an apex health care institution serving predominantly the people of North Karnataka. A retrospective analysis of blood donors over a period of nine years (2007-2015) was done to assess the seroprevalence and the trend of hepatitis B infection among them. ELISA was used to detect the hepatitis B surface antigen in the donors as a marker of infection. Results: A total of 80,312 blood donors were undertaken for the study. About 1613 (2%) were positive for HBsAg, which falls under the “intermediate prevalence (2%-7%) zone” as per World Health Organization (WHO) guidelines. An increasing trend in first five years (2007-2011) and then decreasing trend over next four years (2012-2015) was observed in the present study. Replacement donors and male blood donors showed significantly higher seropositivity compared to voluntary donors and female donors respectively. Conclusion: North Karnataka has an intermediate prevalence of hepatitis B in blood donors with increasing trend in initial five years and decreasing trend over the last four-year period.

Keywords: HBsAg, Seroprevalence, Blood donors, Hepatitis B

Introduction

Hepatitis B virus (HBV) infection is a leading cause of acute and chronic liver disease [1]. The infected person has higher risk of probability for cirrhosis and liver cancer. Approximately 30% of the world’s population or about 2 billion persons have serological evidence of either current or past infection with hepatitis B virus [2]. The prevalence of chronic HBV infection in India ranges from 2% to 10% as shown by different studies [2].

Hepatitis B infection transfusion transmissible infections; which demands for meticulous pre-transfusion testing and screening for HBsAg [3]. Millions of lives are saved every year through blood transfusion; provision of safe blood is of paramount importance for any health care delivery system. Burden of the disease and loss of life resulting from unsafe blood transfusions is very serious problem for the communities in developing countries.

The improved screening and testing of blood donors will significantly reduced transfusion transmitted diseases in most countries. The disease trends and blood assessment can better be done by the study of seroprevalence rate of hepatitis B in blood donors and indexed accurately in general population [4].

The present study was carried out with the aim to find out the seroprevalence of Hepatitis B and its trend among the blood donors a hospital based blood transfusion service set up in northern Karnataka over a period of nine years.
Materials and Method

This prospective observational study was carried out at the Blood Bank (under Department of Pathology), Karnataka Institute of Medical Sciences, a tertiary care Government hospital, retrospectively from January 1, 2007 to December 31, 2015 over a period of nine years. This blood bank is one of the largest blood banks of the state of Karnataka and caters to entire Northern Karnataka. The experiment on data size 80312 donors who donated blood during the nine years were conducted as in given below

**Step I** - Clinically healthy individuals of age group (18-60yrs), body weight (>45 kg), hemoglobin (>12.5 g/dl) and not donated blood in the last three months is the qualification criteria for blood donation in the study group.

**Step II** - Sera of these qualified blood donors are screened for hepatitis B surface antigen (HBsAg) using standard Enzyme Linked Immunosorbent Assay (ELISA) kits.

**Step III** - The procedure of test is followed according to manufacturer’s instruction. Samples showing reactivity are considered positive.

Results

The data of 80312 donors who donated blood during the nine years study period were analyzed. Among them, 77306 (96.25%) were male donors and 3006 (3.75%) were female donors. Replacement donations 50735 (63.2%) were the majority whereas, only 29577 (36.8%) donations were from the voluntary donors (Table 1)

| Year | Voluntary Donors | Replacement Donors | Total Donors |
|------|------------------|--------------------|--------------|
|      | Male | Female | Male | Female |              |
| 2007 | 3083 | 319    | 5006 |      52 | 8460         |
| 2008 | 2728 | 263    | 5314 |      71 | 8376         |
| 2009 | 2340 | 183    | 7908 |      72 | 10503        |
| 2010 | 2271 | 183    | 5980 |      83 | 8517         |
| 2011 | 3072 | 277    | 5338 |      33 | 8720         |
| 2012 | 4667 | 345    | 4180 |      22 | 9214         |
| 2013 | 2959 | 299    | 5119 |      48 | 8425         |
| 2014 | 3291 | 312    | 5003 |      54 | 8660         |
| 2015 | 2704 | 281    | 6343 |      109 | 9437         |
| Total| 27115| 2462   | 50191| 544   | 80312        |
Table 2: shows the seroprevalence of HepB among replacement donors is 2.32% which is comparatively higher than the seroprevalence among voluntary donors (1.46%). This difference was found to be statistically highly significant (p<0.0001). The seroprevalence of HepB among male donors was 2.06% as compared to only 0.56% among female donors, which was statistically highly significant (p<0.0001). The overall prevalence in 80312 blood donors was 2%.

Table 2: Seroprevalence of Hepatitis B in different categories of blood donors.

| Variables       | Total   | HBsAg positive No. (%) | Chi square | P value |
|-----------------|---------|------------------------|------------|---------|
| Type of Donor   |         |                        |            |         |
| Voluntary Donor | 29577   | 432 (1.46%)            | 70.75      | <0.0001 |
| Replacement Donor | 50735 | 1181(2.32%)            |            |         |
| Total           | 80312   | 1613(2)%               |            |         |
| Gender of Donor |         |                        |            |         |
| Male            | 77306   | 1596(2.06%)            | 32.28      | <0.0001 |
| Female          | 3006    | 17(0.56%)              |            |         |
| Total           | 80312   | 1613(2%)               |            |         |

Fig 1: shows the trend of seroprevalence of Hepatitis B in the nine years study period. As shown, the seroprevalence of Hepatitis B among blood donors was 1.87% in the year 2007, 1.75% in 2008 and 1.81% in 2009. However there was an increase in the seroprevalence through the first four years till 2011 and then showing a significant decrease in the trend of seroprevalence by the end of study period i.e ; 2015.

![Seroprevalence of Hepatitis B](image)

Fig-1: Trend of Seroprevalence of Hepatitis B in the study period.

Discussion

In the present retrospective study, a total of data of 80312 blood donors were analyzed. Majority of the donors were males (96.25%) and the rest 3.75% were female donors. Similar findings observed by other studies include Fernandes et al [3], Rose et al. [4] in Vellore, Arora D et al [5] in Southern Haryana, Singh K et al [6] in Coastal Karnataka, Pahuja et al [7] in Delhi and Singh B et al [8] noting more than 90% of the male donors. However, the statistical analysis (chi-square test) revealed the difference in the seroprevalence according to the gender to be significant (p value <0.0001). A significantly higher HBsAg seroprevalence in males than in females is also reported in other studies [8, 9]. In the present study, of the total blood donors Voluntary Donors constituted 36.8 %, while Replacement Donors were 63.2%. It is
shown that replacement donors constitute the largest group of blood donors in India [10], reflecting the lack of awareness amongst the general population. This is similar to study done by Singh et al. (82.4%) [6], Kakkar et al. (94.7%) [12], Pahuja et al. (99.48%) [7] and Arora et al. (68.6%) [13]. In contrast study done by Bhattacharya et al [14] who has noticed a predominance of Voluntary Donor.

The present study revealed that HBV infection was more prevalent among replacement blood donors than voluntary donors as noted in the study of Sonwane et al. and Singhvi et al. [15, 16]. According to India’s Drugs and Cosmetics Act (1945), each blood unit has to be tested for hepatitis B virus infection [17]. In our study the overall prevalence of Hepatitis B was found to be 2%, comparable to study done by Sri Krishna et al. [18] in Bangalore. India has been placed in the intermediate zone of prevalence of hepatitis B by the World Health Organization (2–7% prevalence rates) with a HbsAg prevalence rate of 1–2% reported by Lodha et al. [7].

Supporting this, HbsAg prevalence in Punjab blood donors was 1.7% [19], while Rajasthan had 3.44% [20] and Delhi had 2.23% [7]. In Karnataka, coastal area [6] had 0.62% of HBV seropositivity. Singh et al. have reported a HbsAg prevalence of 1.8% whereas Joshi and Ghimere have reported a prevalence of 2.71% in healthy Nepalese males [8, 9]. On the other hand, the prevalence of HBV infection is lower in the United States and Western Europe (0.1–0.5%) and is reported to be higher, 5–15% in South East Asia and China [7].

One of the greatest challenges of transfusion medicine is the prevention of transmission of infectious diseases through blood transfusion.8617 donors donated at St. Johns Medical College Hospital Blood bank from 1st. September 1997 to 31st August 1998. Srikrishna et al reported that seropositivity among donors for HIV was 0.44%, for HBsAg 1.86%, for HCV 1.02% and for VDRL 1.6% [18].The magnitude of hepatitis to be far more than that of HIV. Hence testing for HCV routinely is recommended.

Behal et al in their study showed that out of 20,000 donors, 450 (2.25%) were HBsAg positive (95% confidence interval (CI), 2.0445-2.4554). Higher prevalence of HbsAg was found among males (440/19235) than females (10/765). The age specific prevalence rose from 1.78% (108/6058) in donors aged 19-25 years to a maximum of 3.03% (96/3161) in donors aged 35-45 years and decreased in older age groups. The peaks were detected in male donors aged 35-45 years and in females aged 25-35 years. Rh-negative blood group donors (21/873) and Rh-positive group donors (429/19127) had almost equivalent prevalence rates of HBsAg. HBsAg was more prevalent in blood group B donors (174/7426) and less prevalent in AB blood group donors (38/2032) [22].

A retrospective review of donor’s record covering the period between 2004 and 2008 at the blood bank, JSS Hospital, Mysore was carried out. All samples were screened for HIV, HBsAg, HCV, syphilis and malaria. Of the 39,060, 25,303 (64.78%) were voluntary donors and the remaining 13,757 (35.22%) were replacement donors. Pallavi et al reported that overall prevalence of HBV, HbsAg, HCV and syphilis were 0.44, 1.27, 0.23 and 0.28%, respectively. No blood donor tested showed positivity for malaria parasite.

Majority were voluntary donors with male preponderance. In all the markers tested there was increased prevalence of TTI among the replacement donors as compared to voluntary donors [21]. With the implementation of strict donor criteria and use of sensitive screening tests, it may be possible to reduce the incidence of TTI in the Indian scenario.

The present study revealed a decreasing trend in seroprevalence was noticed over nine years study period. The lower prevalence and decreasing trend may be a result of several factors. The awareness about the disease and modes of prevention may be one reason for the declining trend in HBV infection. Secondly, the implementation of National Blood policy with uniform guidelines and pre-donation counseling and strict donor selection criteria help in excluding the possibly infected donors. The absence of HBsAg in blood donors may not be sufficient to ensure the lack of circulating HBV and hence there are chances of missing occult HBV infection

Conclusion

Present study showed that most of the donors were replacement donors with male preponderance. There was increased Hepatitis B positivity rate amongst the replacement donors as compared to the voluntary donors. Ensuring the safety of patients by reducing the residual risk of transfusion transmitted hepatitis is the concern of every transfusion center. The decreasing trend of seropositivity reflects the effective safety
strategy among general population and transfusion medicine services. Apart from these, other factors like public awareness, prohibition of professional blood donation have also contributed to the decrease in trend of Hepatitis B.

There should be an establishment of a nationally coordinated blood transfusion services with the implementation of strict donor selection criteria, use of sensitive screening tests and establishment of strict guidelines for blood transfusion may be helpful to further reduce the incidence of Hepatitis B in India.

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