



STUDY OF PREVALENCE OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN BLOOD DONOR POPULATION BORN PRIOR TO AND AFTER IMPLEMENTATION OF HBV VACCINATION IN KERALA, SOUTH INDIA

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ABSTRACT

BACKGROUND: Since 1995 Hepatitis B vaccination became a part of Extended immunization Program (EIP) in India, neonates started getting immunoprophylaxis against Hepatitis B virus. Since vaccination started recently, exact prevalence of immunized persons were not available, but anyway vaccinated blood donors over 18 years old are progressively increasing

MATERIALS AND METHODS: In this study 2400 blood donors were screened for HBsAg by enzyme linked immunosorbent assays, among the donor blood samples which are positive for HBsAg were noted. Various demographic patterns of blood donor were analyzed. To know about impact of vaccination on prevalence HBV infection among donors who born after the implementation of mandatory HBV vaccination schedule was compared with blood donors those who are born before HBV vaccination schedule

RESULTS: Among the blood donors overall prevalence of HBV infection was 0.75% HBsAg. HBV vaccinated blood donor were protected from getting disease, showing P value of 18 years (0.07), 19 years (0.01), 20 years (0.02)

CONCLUSION: Young blood donors born after implementation of universal HBV vaccination in India presented higher prevalence of HBsAg but lower incidence of HBsAg seroconversion than older. HBV vaccine boosting for adolescents at 15–17 years old prior to reaching blood donor age may improve blood safety.

KEYWORDS : Enzyme Linked Immunosorbent Assays, Immunoprophylaxis, Hepatitis B, Blood donor**INTRODUCTION**

Hepatitis B virus (HBV) infection is becoming significant communicable infection and major challenge to health. In developing countries like India, prevalence of hepatitis B is high. Chronic carriers of HBV infection are people with detectable surface antigen (HBsAg) at six months interval. In India the prevalence of chronic HBV carriers is reduced from 3.8% to 2.1% in the general population. Following nationwide implementation of HBV vaccination the prevalence of HBsAg in children <5 years was 1%¹. Even though HBV vaccine acceptance progressively increased between 1995 and 2000 from 36 to 75% then reached a plateau phase up to 92% in 2005. Recent reports showed an average compliance of vaccination is >90% in total population. Age below 20 years leading to a significant decline. HBsAg prevalence (3.8%) below the age of 20 and (10.26%) in 20 to 60 years^{2,3}. Testing of HBsAg in blood donors as a part of screening test reduced the chance of HBV transmission by blood transfusion. But this screening methods are not able to identify pre-seroconversion window period infection (WPI)⁴. Occult HBV infection (OBI) which is identified as an absence of serological detectable HBsAg in blood circulation but presence of HBV DNA in blood⁵. For HBV DNA detection yield of 1:1000- 1:20,000 in OBI carriers attained by nucleic acid testing (NAT)⁶. Blood samples less than 200 copies of HBV DNA load are not sufficient to pick up in NAT testing⁷. Universal vaccination has provided a decrease in chronic HBV carrier rates and disease burden^{8,9}. Since neonatal vaccination started world wide, HBV vaccinated people are slowly becoming the predominant part of blood donors and thus improving the blood safety¹⁰. This study, provide a comprehensive analysis of HBsAg screening in blood donors using immunoassay for a period of one year (2015 January to 2015 December). Donors were categorized according to type donation, gender, age, vaccination status and analyzed the significance of prevalence in hepatitis B infection before and after the implementation of HBV vaccination

MATERIALS AND METHODS

Study population : Blood donors who were recruited for giving blood in institution based blood bank in south kerala between 1/1/2015 and 31/12/2015 were enrolled in this study.

Sample size : 2400

Study method: Cross sectional study

Donors were voluntary donors and non-remunerated replacement donors. Donors who gave blood for the first time was labeled as first time donors and those who are donated blood more than one time named as repeat-donors. EDTA blood samples were collected from blood donors for screening. A pre-donation questionnaire given to donors. After pre-donation counseling and medical examination blood was collected from the donors, and screening samples were tested for HBV infection using third generation ELISA (Transasia). The initially reactive samples of HBsAg were re-tested with same kit but not with same EDTA sample rather with direct sample from blood collection

bag. If both test become reactive, then blood donor considered as HBsAg positive.

Statistical analyses: SPSS software (version 16.0) was used. Categorical variables were compared by using Fisher's exact test. $P < 0.05$ were considered statistically significant

RESULT

During the study period total 2400 blood donors were donated, among them male were 86.75% and females 13.25%, first-time donors 16.86% and repeat-donors 83.14%. Overall prevalence of HBsAg prevalence was 0.75%. The data were arranged according to donor type (first-time or repeat), gender or type of blood donation (TABLE 1). Prevalence of HBsAg among first-time donors was higher than in the repeat-donors, male donors were than in female donors.

TABLE – 1 Demographic characteristics of blood donor

Donors of various categories	Number	Percentage
Male	2082	86.75%
Female	318	13.25%
First time donor	405	16.86%
Repeated donor	1995	83.14%
Voluntary donor	2213	90.21%
Replacement donor	187	9.79%
HBV vaccinated	448	18.67%
HBV nonvaccinated	1952	81.33%

Prevalence of HBsAg among blood donors born before and after implementation of immunization was analyzed to study the impact of national vaccination program. Implementation of mandatory vaccination started in year 1995. Vaccinated and non-vaccinated blood donor populations were selected through pre-donation questionnaire. Blood donors born in 1995, later donated blood in 2013 or subsequent years were considered as hepatitis B vaccinated blood donor. If date of birth of blood donors is before 1995, donated blood were considered as non-vaccinated donors. HBV infection were more among the non vaccinated donors compared to vaccinated and the difference was statistically significant (TABLE 2)

Table 2 Prevalence Of Hbsag In Donors Born Before And After 1995 Tested At The Same Ages

Age year	Born after 1995 HBsAg+/total	Percentage	Born after 1995 HBsAg+/total	Percentage	P value (Fisher exact test)
18	1/425	0.24%	5/204	2.45%	0.07
19	3/405	0.74%	10/178	5.62%	0.01
20	3/560	0.54%	3/631	0.48%	0.02
All age	8/1008	0.8%	17/1387	1.23%	0.003

DISCUSSION

The study occurs in a coastal area of southern part of Kerala, where more than 22 lakhs of people were living. In the study overall prevalence of HBsAg in blood donors was 0.75%. HBV prevalence observed was significantly higher in first-time donors, male donors. In repeated donor prevalence of HBsAg is low and the changes are may be because of new infections appearing or higher sensitive methods of transfusion screening assays. The most noticed result in this study was high prevalence of HBsAg in vaccinated first time donors (4.1%) aged 18–20 years than in non-vaccinated donors in the same age group (3.81 %) found to be significant since P value is 0.004. Prevalence of HBsAg in first-time donors born after 1995 seemed to increase with age compared with that of donors born earlier. These kind of amazing results can be evaluated by examining the expected rate of vertical transmission of HBV before 1995 and after 1995¹¹. This result was compared with the trend in transmission of HBV infection in India as well as other countries among vaccinated donors. It showed a comparable result, in China the rate of HBV vaccination was 30 % between the year 1987 and 1992¹². Assuming a prevalence of HBsAg of 15 % in the Guangdong province and a 40 % rate of vertical transmission with 70 % non vaccinated population¹³. The predicted incidence of HBsAg in children was 4.3 %^{14, 15}. Since hepatitis B vaccination became compulsory for all neonates within 24 hours of birth, decreased the HBV prevalence in children to 1 % . Those vaccinated children with low level of anti-HBs are susceptible to infection leading to occult HBV infections. HBV genotype A2 has vaccine efficacy. Current hepatitis B recombinant S protein vaccines are of genotype A2. A study found that 6 of 9 vaccinated blood donors were identified as OBIs¹⁶. Six of these donors had antiHBs exposed to non-A2 strains . Another study conducted in vaccinated blood donors revealed a prevalence of anti-HBc increasing with age¹⁷. Many studies showed the decline and the high percentage of undetectable of anti-HBs in vaccinated people over 14 years of age, including blood donors^{18, 19, 20}. So booster vaccine in adolescents should be considered for its efficacy. However the justification of such strategy remains controversial and its implementation still under consideration

CONCLUSIONS

In this study, we observed that the prevalence of HBsAg was 0.75 % .The modest differences in HBsAg prevalence prior to or since 1995 can be explained by the slow and progressive increase in vaccination compliance. For transfusion safety, HBV booster vaccination between age 15 and 17 years should be considered.

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