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Research Article

Trend of Hepatitis B Surface Antigen (HBsAg) among blood donors at the blood bank of a tertiary care referral teaching hospital in Southern India

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ABSTRACT

Background: Blood is a scarce, but lifesaving resource; it is also the most efficient vehicle for the transmission of Hepatitis B virus (HBV). Hence there is a need for accurate screening of hepatitis B surface antigen (HBsAg) among blood donors. The present study was designed to assess the seroprevalence of HBsAg, among the voluntary and replacement blood donors in the blood bank of a tertiary care referral teaching hospital in Andhra Pradesh.
Methods: This is a prospective cross sectional analytical study conducted over a period of one and a half year. A total of 9909 donor blood samples were screened for HBsAg status using enzyme linked immunosorbent assay (ELISA). The reactive samples have been tested in duplicate using different kit. The samples reactive in all three times were considered positive. The samples which were reactive only in first test were labeled as false positive.
Results: Out of 9909 blood donors screened, 255 (2.6%) were initially reactive and 219 (2.2%) were reactive after triple testing.
Conclusions: Our study showed similar HBsAg seroprevalence as that reported by World Health Organization (WHO) statistics in intermediate zone. But there was a mild increase in HBsAg seroprevalence among donors belonging to rural areas in our region compared to the urban donors.

Keywords: Hepatitis B Surface Antigen, Seroprevalence, Blood donors

INTRODUCTION

Hepatitis B virus (HBV) was among the first virus known to be transmitted by blood and blood products.[1] India, as reported to be an endemic country for human immunodeficiency virus (HIV) infection and HBV infection, screening for these viruses poses a serious challenge for blood banking community. The most reliable method for preventing HBV transmission is screening the blood donors for the presence of major part protein of the virus, Hepatitis B surface antigen (HBsAg) in their serum.[2] Screening of donors for HBsAg has been introduced from early 1970s.[3] It is one of the mandatory tests to be carried out for all blood donors. The reports about the prevalence of HBV in the blood donors of Andhra Pradesh are scarce. The review of records of our blood bank for the past three years showed varying rates of HBsAg seroreactivity from 2% to 3.5%. Hence, this study was planned to carry out the repeat testing of the donors to confirm the HBsAg seroreactivity and initiate an attempt for their counselling before deferral.

METHODS

This prospective cross sectional analytical study was conducted over one and half year period from March 2011 to September 2012 in the Department of Immunohematology and Blood Transfusion attached to a

tertiary care referral teaching hospital in Andhra Pradesh. A total of 9909 blood donors who were eligible to donate blood as per the criteria laid down by the Drugs and Cosmetics act, 1940 and Rules, 1945[4] were included for the study after getting a written informed consent. Prior approval from the institutional ethics committee was obtained.

The demographic details like donor's age, gender, rural/urban status, category of blood donation (voluntary or replacement) and history of past donation were recorded. A total of 9,909 donor blood samples were screened by Central Drugs Standard Control Organization (CDSCO) approved enzyme linked immuno-sorbent assay (ELISA) kit Hepalisa (J Mitra & Co Pvt. Ltd. India) and Hepanostika HBsAg Ultra (bioMeriuex, 376 Chemin de l'Orme, 69280 Marcy-l'Étoile, France). It is based on "sandwich ELISA principle". If Hepatitis B surface antigen was present in human serum/ plasma, an intense yellow colour develops in the well at the end of procedure. If the sample is free from the above mentioned antigen, no colour is formed.

The blood units which found to be seroreactive were discarded as per National Biomedical Waste Management policies. The sample was labelled as false positive if it was reactive in the first ELISA test, but non- reactive in later duplicate test using different kit. Any sample reactive in the first ELISA test and has repeatable reactivity in at least one well was considered positive. Test ELISA procedure performed by following manufacturer's instructions strictly. The HBsAg seroreactivity during the study period was compared with previous years the data of which was obtained from blood bank records.

Statistical analysis

The various variables studied included age, gender, urban/rural status, type of donation (voluntary or replacement), occupation and seroreactive status for HBsAg. Descriptive statistics for categorical variables were performed. The association between two categorical variables was evaluated by Chi-square test using WinPepi software (Windows statistical analysis software for Epidemiologists, Version 11.8.). For all statistical analyses performed, a p-value of less than 0.05 was considered significant.

RESULTS

Out of the 9,909 blood donations screened, 255 (2.6%) were found to be seroreactive for HBsAg in the first assay. When the reactive samples were further tested by the second ELISA in duplicate, 219 (2.2%) were found repeat reactive (seropositive as per NACO criteria) and 36 (0.4%) samples were negative. On repeat testing we were able to eliminate the false positives which accounted for 14.12% of all HBsAg reactive in first ELISA (Table 1)

Table 1: Comparison between HBsAg reactivity by single/triple testing of donor samples during previous years.

Year	Total donors screened	Total HBsAg reactive	p-value
	No. (%)	No. (%)	
Mar 2011-Sep 2012 (Single testing)	9909	255	0.104
Mar 2011-Sep 2012 (Triple testing)	9909	219	1.000

Of the 219 seropositive blood donations, 217 (99.08%) were from males. We found no statistically significant difference between the prevalence of HBsAg among males and females (p=0.097) (Table 2). Among the triple reactive donors, 165 (75.34%) were voluntary and 54 (24.66%) were replacement. There was no statistically significant difference between HBsAg seroreactivity among the voluntary and replacement donors (p=0.682). There was statistically significant difference between the seropositive donors from rural and urban areas (p<0.001). Out of the 219 seropositive donors, 100 were from urban areas (45.66%) (Table 2).

Table 2: Distribution of HBsAg seropositivity among various groups.

Variable	Seropositivity No.(%)	Seronegative No.(%)	Total No.(%)	p-value
Male	217 (2.2)	9349 (94.35)	9566 (96.53)	
Female	2 (0.02)	341 (3.43)	343 (3.47)	0.097
Voluntary	165 (1.66)	7182 (72.48)	7347 (74.15)	
Replacement	54 (0.55)	2508 (25.31)	2562 (25.85)	0.682
Rural	119 (1.20)	3866 (39.02)	3985 (40.22)	
Urban	100 (1.01)	5824 (58.77)	5924 (59.78)	<0.001

Among seropositive donors, 112 (51.14%) were in the age group of 21-30 years, 20 were in the age group 18-20 years, 65 were in the age group of 31-40, 18 were in 41-50 years and 4 were in 51-60 years age group. Though most donors are in the age group of 21-30, we found no

statistically significant difference between the categorized age groups and HBsAg prevalence (p=0.2348) (Table 3). 36 (14.11%) false seroreactive samples were detected after triple testing, but there was no statistically significant difference between single and triple testing and detection of HBsAg (0.104). The HBsAg seroreactive donors have declined over the years (Table 4) and there is a statistically significant decline in HBsAg seroreactive rate even without triple testing (p=0.045).

Table 3: Prevalence of HBsAg among different age groups.

Age group (years)	Seropositivity No.(%)	Seronegative No.(%)	Total No. (%)	p-value
18 – 20	20 (0.20)	1269 (12.80)	1289 (13.01)	0.1182
21 – 30	112 (1.13)	5575 (56.26)	5687 (57.40)	0.2348
31 – 40	65 (0.66)	2150 (21.70)	2215 (22.35)	0.7113
41 – 50	18 (0.18)	587 (5.93)	05 (6.10)	0.7492
51 – 60	4 (0.04)	109(1.10)	113 (1.14)	1.0000

Table 4: Comparison between HBsAg reactive over the years Mar 2008 – Sept 2012.

Year	Total donors Screened	Total HBsAg reactive No. (%)	p-value
Mar 2008 – Feb 2009	5868	187 (3.1)	0.045
Mar 2009 – Feb 2010	5289	157 (3.0)	0.53
Mar 2010 – Feb 2011	5329	159 (3.0)	0.137
Mar 2011 – Sept 2012	9909	255 (2.6)	2.6

DISCUSSION

The first step in the assessment of blood safety of any blood transfusion service is the evaluation of the seroreactivity of the donated blood for transfusion transmitted infections. Screening for HBV infection is one of the mandatory tests that are carried out routinely. The primary purpose of screening donor blood for infectious disease markers is to prevent pathogen transmission to the recipients.

The overall prevalence rate of HBsAg seroreactivity is 2.2% as observed in our study. This is comparable to the observations of Sinha SK et al., (2012)[5] i.e. 2.27% and Rani K *et al*., (2011) i.e. 2.14%.[6] There is slight variation when compared to the prevalence rate reported by others like Mathai J *et al*., 3.1%[7] and Lavanya V *et al*., (2012) 3.5%.[8] Comparatively, a lower prevalence was observed by others, a prevalence of 0.29% reported by Makroo *et al*., (2008)[9] after a multicenter evaluation in blood donors by simultaneous serological and individual donor nucleicacid amplification (ID-NAT) testing; 0.34% by Fernandez H *et al*., (2010),[10] 1.37% by Jain R, Gupta G (2012).[11] The prevalence of HBsAg either higher or lower observed may depend on actual prevalence of HBV infection in general population, repetition of the initial seroreactive samples and technical errors causing high or low absorbance value.

It has been reported that the seroprevalence of HBsAg among blood donors is lower (1.71%) in our neighboring country Pakistan (Karachi).[12] Nigeria has shown higher prevalence of hepatitis B antigen in blood donors i.e. 15% as reported by Ado A *et al*., 2010,[13] it could be due to the higher prevalence of HIV, such countries come under high endemic countries. HIV and HBV are known to be transmitted sexually.

As shown in the Table 1, voluntary donors constituted 74.1% of our donors; this rate of voluntary donation is in accordance with the percentage of voluntary blood donation in India (79.4%) for the year 2010-2011 (NACO, Annual report 2011). There was a marginal increase in prevalence rate of HBsAg in these voluntary donors (2.2%) compared to replacement donors (2.1%). This is comparable to the observations of Rani K *et al*., 2011.[6] They compared the prevalence rate in these categories of donors before and after implementation of the new NACO definition (2009) of voluntary donors and reported that the broadened NACO definition dilutes the difference in the prevalence rates between replacement and voluntary blood donors. Our observation is coinciding with the report of Kakkar N *et al*., (2004)[14] from Ludhiana, Punjab. The prevalence of TTIs was marginally high among voluntary donors (3.3%) as compared to replacement donors (2.9%) and they expressed the opinion that voluntary donation in their study was not voluntary in the real sense.

In our study we observed a seroreactivity rate of 2.26% and 0.58% among male and females respectively. The lower prevalence among female, is due to lower number of donors in that group. Singh K *et al*., (2010) reported prevalence HBsAg, 0.65% in males and 0.25% in females.[15] Kochhar AK *et al*., (2012) 1.35% and 0.48% among male and female donors respectively.[16]

We observed higher prevalence of HBsAg reactivity (3.5%) in blood donors aging more than 50 years when compared to the donors within 20 years (1.5%). This coincides with the observations of Fathi Abed Al-Gani *et al*., 2011.[17] The study by Patil AV *et al*., (1996)[18] and Rodenas JG *et al*., (2006) [19] reported the higher prevalence of HBsAg in donors older than 38 years of age. This has been explained on the basis of increased exposure to this virus with age. In the younger age group

the less prevalence may be due to the vaccination program implemented in certain countries.

In contrast a few studies have reported higher prevalence in younger age group. Murugan S *et al.,* (2010) reported 15.4% among younger age groups.[20] Studies by Singh K *et al*., (2009) from coastal Karnataka showed majority of seropositive donors are younger than 35 years of age.[15] A report by Sinha SK *et al*., (2010), observed more number of seropositive donors over the age of 30 years[5]. The increased prevalence reported in the younger population may be due to the evolving practices like tattooing, promiscuous behaviour seen in some individuals.

We have observed a higher prevalence (2.99%) of HBsAg seroreactivity in blood donors coming from rural areas compared to those from urban areas (1.68%). Similar prevalence has been reported in patients from rural communities by Balaji N *et al*., (2009),[21] from the adjacent state Tamil Nadu. They have reported a frequency of 1.79% compared to the lower prevalence from periurban patients 1.52%.

The reasons for higher frequency in rural population have been attributed to the poor safe injection practice, high risk sexual behavior, transmission in childhood and lack of repeat testing for this virus[22]. Here it has to be emphasized that, the major route of HBV transmission is through the parenteral route. Sonwane BR *et al*.,[23] have studied the prevalence of the viral infections in rural blood donors and reported a rate of 4.07% of HBsAg reactivity.

We observed a decreased trend in the seroprevalence of HBsAg during the last four years. A statistically significant decline in the prevalence of HBsAg is noted during the study period (2.2%) when compared to statistical data from previous year Mar'2008- Feb'2009 (3.1%). This could be due to considerable increase in public awareness during recent years and stringent donor selection. Similar decrease in trend was observed over successive three years (0.68% to 0.56%) by Singh K *et al*., (2009)[15] and (3.54% to 3.26%) by Khan NU *et al*., (2010).[24]

The seroprevalence for HBsAg in the blood donors at our blood bank was observed to be 2.2%. There was a marginal increase in the prevalence of infection noted in voluntary donors (0.1%); this is considered to be due to the inclusion of family members in the category of voluntary donors. A slightly declining seroprevalence of 0.83% is observed than that of the previous years. This may be due to the elimination of false positives by repeat testing.

Stringent donor selection, proper counseling and deferral/self exclusion may reduce the seroreactivity in donated blood and wastage of resources. Implementation of more sensitive tests such as NAT for HBV that detects HBV infection earlier during the window period will further decrease the risk of transfusion transmitted HBV and improve the blood safety.

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