

SEROPREVALENCE AND RISK FACTORS FOR HEPATITIS-B VIRUS INFECTION AMONG GENERAL POPULATION IN NORTHERN INDIA

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ABSTRACT – Background - Infection with hepatitis-B virus has been a significant cause of morbidity claiming more than a million lives every year. Epidemiological data reveals that there are 360 million carriers of hepatitis-B virus throughout the globe and 78% of the world populations' hail from Asia. Though several studies from Indian sub-continent have provided an estimate of the prevalence of this viral infection, there exist only few studies, which reflect the status in the general population. **Aim** - The present study was designed to investigate the prevalence of hepatitis-B infection in North Indian general population. **Methods** - The study population comprised of 20,000 healthy blood donors who were screened for hepatitis-B surface antigen (HBsAg) status using third generation ELISA kit. Seroprevalence rate of seropositive donors was calculated and stratified by age, sex and blood groups. Statistical analysis was performed using tests of proportions, chi-square and confidence interval. **Results** - The 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). **Conclusion** - It was found that variables including gender and age were significantly associated with HBsAg positivity. HBsAg positivity in our population was statistically not associated with ABO blood groups.

HEADINGS – Hepatitis-B virus. Hepatitis B surface antigen. Blood donors. Seroepidemiologic studies. Risk factors. India.

INTRODUCTION

Hepatitis B virus (HBV) infection is one of the major global health problems. Of the approximately 2 billion people, who have been infected worldwide more than 350 million are chronic carriers of HBV⁽³⁴⁾. HBV infection accounts for 5,00,000 to 1.2 million deaths each year⁽²²⁾ and is the 10th leading cause of death. The prevalence of HBV infection varies markedly in different geographic areas of the world. In developed countries like Northern Europe and America, HBV infection occurs in less than 1% of the population of these countries. In developing countries of Asia and Africa, particularly those of Far East and South Africa, HBV infection occurs in 5%-10% of the general population. India is considered to be in the region of

intermediate endemicity, with nearly 3%-4% of the population infected by the virus⁽⁶⁾.

Data on burden of HBV infection in India come primarily from studies on HBsAg seroprevalence. A large number of studies on the epidemiology of HBV infection have been carried out in this country over the last two decades. There are several levels of variability amongst these studies which include the sample size, the methodology for assay of HBV serological markers, the age group covered, general population sample versus blood donors, risk-population samples, ethnicity and geography of the study groups. All these factors have also been shown to influence the prevalence of HBV infection. Of the studies among various groups, those among voluntary blood donors are most closely representative of the rates in the general population.

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Though these studies have used laboratory tests with different sensitivity and specificity rates, they provide a good estimate of HBV burden in the country.

Earlier studies have reported that HBsAg prevalence among blood donors ranged from 1% to 4.7%⁽¹⁾. There are conflicting reports on the prevalence rates of HBsAg in India. Adequate data on age, sex and blood group specific prevalence is also lacking. Therefore the present study was undertaken to estimate the age, sex and blood group specific prevalence of HBsAg in blood donors, representing general population in Northern India.

METHODS

Study population and laboratory tests

Twenty thousand subjects visiting Ganesh Shankar Vidyarthi Memorial (GSVM) Medical College, Kanpur, India, from March 2002 to June 2006 were included in the present study. Three milliliter blood sample from apparently healthy blood donors belonging to all socioeconomic group was collected in EDTA vacutainers. The blood bank caters to a wide area of Northern India therefore healthy donors comprised of general population. A thorough clinical history, medical examination and selection of donors were done; prior obtaining signed consent form from all the donors. All the donors were screened for hepatitis-B surface antigen (HBsAg) test by third generation enzyme linked immunosorbent assay (HBsAg ELISA 3.0, Span Diagnostics, India) along with other mandatory tests for blood donation. Blood group of each donor was tested and the donors were categorized according to their respective blood groups, sex, age and correlated with risk factors.

Statistical analysis

The data was analyzed statistically, using appropriate statistical tests like tests of proportions, Chi-square tests and confidence interval. *P* value was calculated using SPSS Software. A *P* value <0.05 was considered statistically significant. 95% Confidence Interval of the proportions of HBsAg prevalence was determined as follows:

$$P \pm (\sqrt{pq/n}) * Z_{d/2}$$

where *P* = proportions of population found positive for HBsAg
 $q = 1-p$
 n = total number of cases
 z = standard normal variate (1.96)
 d = degree of freedom

RESULTS

Overall and gender specific prevalence

The overall prevalence of HBsAg among blood donors aged 19-55 years was 2.45% ($n = 20,000$) (95% CI: 2.0445-2.4554). The prevalence of HBsAg in males was 2.28% (440/19235) compared to 1.30% (10/765) in females. The difference was found to be statistically significant ($P = 0.0206$) (Table 1).

Age specific prevalence

HBsAg seroprevalence increased with age, 1.78% in 19-25 year age group to 3.03% in 35-45 year age group. The difference

TABLE 1. Relationship between HBsAg seropositivity and selected variables among general population in Northern India

Risk factors	HBsAg		95% CI*	<i>P</i>
	n/N	%		
Sex				
Male	440/19235	2.28%	2.0683-2.4917	<i>P</i> =0.0206
Female	10/765	1.30%	0.4974-2.1026	
Age (years)				
19-25	108/6058	1.78%	1.4472-2.1128	<i>P</i> =0.0381
25-35	226/9994	2.26%	1.9685-2.5515	
35-45	96/3161	3.03%	2.4324-3.6276	
45-55	20/787	2.54%	1.4408-3.6392	
Rh-Group				
Rh-positive	429/19127	2.24%	2.0303-2.4497	<i>P</i> =0.7623
Rh-negative	21/873	2.40%	1.385-3.415	
Blood Group				
A	106/4618	2.29%	1.8586-2.7214	<i>P</i> =0.1768
B	174/7426	2.34%	1.9962-2.6838	
AB	38/2032	1.87%	1.2811-2.4589	
O	132/5924	2.22%	1.8449-2.5951	

*Confidence Intervals, N= Total Donors, n= HBsAg positive cases

was found to be statistically significant ($P = 0.0381$) (Table 1). The study showed maximum prevalence of HBsAg at 3.10% (94/3025) in male donors aged 35-45 years and at 1.76% (6/339) in female donors aged 25-35 years. For both genders minimum prevalence was seen in the donors aged 19-25 years. We could not establish any significant association between age and gender in relation to HBsAg positivity (data statistically insignificant) (Table 2).

TABLE 2. HBsAg positivity in association with sex and age

Age (years)	Male			Female		
	n/N	%	95% CI	n/N	%	95% CI
19-25	106/5802	1.82%	1.476-2.164	2/256	0.78%	0.2976-1.8576
25-35	220/9655	2.27%	1.9729-2.5671	6/339	1.76%	0.3602-3.1598
35-45	94/3025	3.10%	2.4824-3.7176	2/136	1.47%	0.5525-3.4925
45-55	20/753	2.65%	1.5029-3.7971	0/34		

Blood group specific prevalence

The prevalence of HBsAg did not vary significantly ($P > 0.05$) and was marginally high among the Rhesus-negative group (2.40%) than those with Rhesus-positive group (2.24%) [$P = 0.7623$]. HBsAg prevalence was higher in blood group B at 2.34% (174/7426) and lowest in blood group AB at 1.87% (38/2032). The difference though was statistically not significant ($P = 0.1768$) (Table 1). The present study showed highest seroprevalence of HBsAg in blood group B (2.39%) and lowest in blood group AB (1.90%) among Rh-positive group. Among Rh-negative group the highest seroprevalence was seen in blood group O (3.65%) and lowest in blood group AB (1.08%) (Table 3). Among male blood donors, HBsAg was found to be more prevalent in O-negative blood group at 3.78% (9/238) and lowest in AB-negative at 1.14% (1/87). Among the female donors, highest seroprevalence of HBsAg was seen in B-positive blood group at 2.04% (5/244) (Table 4).

TABLE 3. HBsAg prevalence according to blood group and Rh group

Blood Group	Rh-Positive			Rh-Negative		
	n/N	%	95% CI	n/N	%	95% CI
A	99/4403	2.24%	2.0170-2.4630	7/215	3.25%	0.8798-5.6202
B	170/7106	2.39%	2.0348-2.7452	4/320	1.25%	0.0329-2.4671
AB	37/1940	1.90%	1.2926-2.5074	1/092	1.08%	1.0321-3.1921
O	123/5678	2.16%	1.7819-2.5381	9/246	3.65%	1.3066-5.9934

TABLE 4. HBsAg seroprevalence in association with blood group and sex

Blood Group	Male			Female		
	n/N	%	95% CI	n/N	%	95% CI
A-Positive	97/4251	2.28%	2.0511-2.5089	2/152	1.31%	0.4977-3.1177
A-Negative	7/204	3.43%	0.9326-5.9274	0/11		
B-Positive	165/6862	2.40%	2.2154-2.5846	5/244	2.04%	0.2662-3.8138
B-Negative	4/306	1.30%	0.6525-1.9475	0/14		
AB-Positive	37/1861	1.98%	1.3471-2.6129	0/79		
AB-Negative	1/087	1.14%	1.0909-3.3709	0/5		
O-Positive	120/5426	2.21%	1.8188-2.6012	3/252	1.19%	0.1489-2.5289
O-Negative	9/238	3.78%	1.3571-6.2029	0/8		

DISCUSSION

Hepatitis-B is found throughout the world, it has no seasonal distribution. The reported prevalence of carrier in different population varies widely from 0.1% in the advanced countries to 20% in the developing nations. The carrier rate is higher in the tropical than in the temperate regions. In South East Asia, roughly 14 to 16 million people are infected with hepatitis B virus every year. Prevalence of hepatitis B varies from country to country and depends upon a complex interplay of behavioral, environmental and host factors. In general, it is lowest in countries or area with high standards of living (eg: Australia, North America, North Europe) and highest in countries or areas where socio economic level is lower (eg: China, South East Asia, South America)⁽⁷⁾.

The study showed 2.25% seroprevalence of HBsAg among blood donors. The frequency of HBsAg seropositivity was found to be lower than that reported in Tamil Nadu 24.5%⁽¹³⁾, Madras 5.5%⁽³⁰⁾, Vellore 7.17%⁽²⁹⁾. The rate was comparable to that reported from Lucknow 2.2%⁽⁵⁾, North India 2.5%⁽²⁵⁾, Mumbai 2.02%⁽⁹⁾, Pakistan 2.21%⁽²⁴⁾, Calcutta 2.8%⁽⁴⁾ and Bangladesh 2.4%⁽¹⁷⁾.

When the results of the present study was compared with those reported from similar blood donors of other countries like Cameroon 11.72%⁽³⁵⁾, Taiwan 4.5%⁽³²⁾, Ethiopia 14.4%⁽²⁷⁾, Mauritania 20.3%⁽²⁰⁾, Thailand 4.51%⁽²¹⁾, Djibouti 10.4%⁽⁸⁾, Mangolia 8.2%⁽³³⁾, this study showed relatively lower prevalence of the hepatitis-B surface antigen whereas countries like Brazil 1.9%⁽²³⁾, Iran 1.07%⁽¹²⁾, Turkey 1.5%⁽²⁸⁾ and US Community 0.15%⁽¹⁸⁾, showed lower HBsAg positivity in comparison to the present study.

Sex specific prevalence

With respect to sex related prevalence, this study showed 2.28% prevalence of HBsAg in males and 1.30% prevalence in females, (statistically significant, $P = 0.0206$). This finding of the present study is in concern with other studies, which demonstrated a higher prevalence of HBsAg among the male population^(2, 3, 11, 15, 26).

The high prevalence of HBsAg infection in male blood donors was responsible for the overall high prevalence in blood donors, which were predominated by male donors. Another important contributing factor responsible for a higher prevalence among the male population of the present study is that plasma disappearance rate for HBsAg in males is lower than females⁽³¹⁾.

Age specific prevalence

The present study revealed significant trend of HBV seropositivity with relation to age. The positivity for HBsAg increased with age. This is comparable with the study conducted by JAYARAM⁽¹⁶⁾. Some other studies have shown similar results^(3, 14, 19, 23). Higher prevalence in older age groups may be attributed to birth cohort effect or iatrogenic factors including vaccinations by the use of unsterilized kits. Further the trend of immunization against hepatitis-B has been introduced in the recent few years. Therefore the older age group population having a higher prevalence of HBsAg detected in the present study is presumptively due to lack of immunization against the disease in their times. In the present study, declining seropositive rates in individuals aged 45 years or over was observed for both genders. Self-selection due to persistent HBV infection may partly account for such tendencies⁽²⁾.

Blood group specific prevalence

The present study showed no significant association between ABO blood group distribution and HBsAg seroprevalence (data not statistically significant $P = 0.1768$). This is in accordance with other studies^(10, 11). However, earlier studies had reported no prevalence of HBsAg in AB blood group donors, whereas the present study reported 1.87% HBsAg seroprevalence. The possible reason for this variance may be a large variation in the sample size.

Higher prevalence of HBsAg in blood group B could be because of the fact that blood group B is more prevalent in our area (37.13%). The study also demonstrated no significant difference in the HBsAg positivity among donors with Rh-negative group (2.40%) and Rh-positive group (2.24%). This slight variation observed may be accorded due to random chance variation.

CONCLUSION

In conclusion, the results of the present study hint at the importance of presenting integrated information and educational programs among these target groups, for preventing and controlling HBV transmission. Further, future surveillance studies warranting investigations for this viral infection in a broader population would enable us to determine strategies for combating the threats caused by hepatitis-B virus. In addition, epidemiologic studies like the present one from different states of India would be helpful to estimate real statistics of hepatitis-B infection in India.

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RESUMO – Racional - A infecção pelo vírus B da hepatite é considerada uma significativa causa de morbidade, responsável por mais de 1 milhão de casos, a cada ano. Dados epidemiológicos revelam que existem 360 milhões de portadores de vírus da hepatite B no mundo e 78% da população natural da Ásia. Embora vários estudos realizados na Ásia sub-continental tenham fornecido uma estimativa de prevalência desta infecção viral, existem poucos estudos que avaliam esta condição na população geral. **Objetivo** - Investigar a prevalência da infecção pelo vírus B da hepatite na população geral do nordeste da Índia. **Métodos** - A população estudada compunha-se de 20.000 doadores de sangue sadios, selecionados através de positividade do antígeno de superfície da hepatite B (HBsAg), utilizando-se o kit ELISA de 3ª geração. A taxa de soroprevalência dos doadores soropositivos foi calculada e estratificada por idade, sexo e grupos sanguíneos. Análise estatística foi obtida usando-se testes de proporções, do qui ao quadrado e intervalo de confiança (CI). **Resultados** - O estudo revelou que dos 20.000 doadores, 450 (2,25%) eram HBsAg positivos (95% CI 2.0445-2.4554). Prevalência maior de HBsAg foi encontrada em homens (440/19235) do que em mulheres (10/765). A prevalência por faixa etária aumentou de 1,78% (108/6058) em doadores entre 19 a 25 anos, para máximo de 3,03% (96/3161) naqueles entre 35-45 anos e decresceu nos grupos de maior idade. Os picos foram detectados em doadores masculinos de 35-45 anos e em mulheres de 25-35 anos. O grupo de doadores Rh negativo (21/873) e o grupo Rh positivo (4299/19127) mostraram taxas de prevalência de HBsAg quase equivalentes. HBsAg foi mais prevalente no grupo de doadores de tipo sanguíneo B (174/7426) e menos no grupo de tipo sanguíneo AB (38/2032). **Conclusão** - Verificou-se que variáveis incluindo gênero e idade foram significativamente associadas à positividade do HBsAg e que esta não foi estatisticamente associadas aos grupos sanguíneos ABO.

DESCRITORES – Vírus da hepatite B. Antígenos de superfície da hepatite B. Doadores de sangue. Estudos soroprevalência. Fatores de risco. Índia.

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