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Seroprevalenceof HBs Ag and HCV in Healthy Blood Donors at a Tertiary Care Hospital in India.

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ABSTRACT

Hepatitis B and hepatitis C threatens safety of the recipients and the community as a whole and are subject of real concern worldwide. To assess the seroprevalence of HBV and HCV among blood donors at a tertiary care hospital-based blood bank in Punjab.7000 blood donors (5450 voluntary and 1550 replacement donors) were studied. All the blood donors were screened for HBsAg and anti-HCV antibodies (third generation ELISA). Seroprevalence of HBsAg and HCV were 0.91% and 0.83% respectively. Seropositivitywas higher among replacement donors than voluntary donors in HBsAg (1.39% vs. 0.79%) and HCV (1.22% vs. 0.72%). Seroprevalence was more in age group 31-40 years and higher in rural area donors. The incidence decreased in repeat donors. Prevalence of HBsAg was higherthan anti HCV. Stringent measures need to be taken including dissemination of information andvigilant donor screening, screening of blood unit with sensitive techniques like NAT,inclusion of antibody to hepatitis B core antigen.
Key words: Blood donors, HBsAg, anti-HCV, voluntary donor, replacement donor.

Key message: Repeat voluntary donors are safest and inclusion of sensitive techniques like NAT, antibodies to HBcAg and HCV RNA for donor screening will improve blood safety further. Educate rural masses about the prevention of viral diseases.

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INTRODUCTION

Hepatitis B and hepatitis C are highly infectious and pose a major public health problem worldwide. The problem in developing countries has increased by the poor economical status of the patients. About 3% of world's population or almost 200 million individuals have chronic HCV infection.[1] The global seroprevalence of HCV among blood donors varies from 0.4-19.2%[2].Approximately 2 billion people in the world have been infected by HBV,[3]350 million of which are chronic carriers representing 7% of total population[4].The virus causes hepatitis of varying severity[5].

The transmission of HBV and HCV occurs mainly through direct contact of blood, IV injections, blood transfusion and sexual relations, the latter, mainly in HBV carriers. The sexual transmission in HCV is controversial[6].Over many years, hepatitis was the main cause of transfusion associated chronic disease, liver cirrhosis, hepatocellular carcinoma and death[7].The discovery of these serious hazards has brought a dramatic change in the behaviour of patients and physicians[8].

Various studies have been conducted in the past that provided data about the seroprevalence of HBsAg and HCV in different parts of the world. This study was conducted to evaluate the prevalence of HBsAg and HCV in healthy blood donors.

MATERIALS AND METHODS

This study was conducted at blood bank of Rajindra hospital (tertiary care hospital) Patiala for a period of 6 months from January 2010 to June 2010. A total of 7000 blood donors (voluntary and replacement) who donated blood in blood bank and various outdoor voluntary blood donation camps were included in the study. They were carefully selected for donation after complete physical examination and satisfactorily answering the donor's questionnaire. A thorough medical history was taken to ensure that the donor is free of all communicable diseases. The exclusion criteria used were history of jaundice, anemia, malaria, drug addiction and repeated blood transfusion and any evidence of cardiac, renal and pulmonary disease.

Blood samples from donors were tested for HBsAg and antibodies against HCV. The methodology used was third generation ELISA (Enzyme Linked Immunosorbent Assay), which is a quantitative assay having a sensitivity ranging from 90-97%.The use of third generation ELISA shortens the pre-seroconversion window period but does not distinguish between acute, chronic or resolved infection. Any serum found reactive by the first assay was tested using second assay based on a different antigen preparation and/or different test principle. The serum that is reactive by both tests will be considered HBsAg/HCV positive. The serum that is non-reactive in the first test will also be considered HBsAg/HCV negative. The serum that is reactive by first test and non-reactive by second test will also be considered as negative for surveillance. The samples will be tested by third generation ELISA for these viral markers. The relation of seropositivity with age, sex, voluntary/replacement, first time donation & second time donation will be studied. The results were analysed statistically and interpreted.

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RESULTS

A total of 7000 blood donors were screened for HBsAg and anti-HCV. Out of 7000 donors 6535 (93.35%) were males and 465 (6.65%) were females with male to female ratio of 14.05:1. About 77.85% (5450/7000) of donors were voluntary donorsand rest 22.15% (1550/7000) were replacement donors. The overall seroprevalence of HBsAg was 0.91% and that of HCV was 0.84%.Seroprevalence of HBsAg was higher among replacement donors 1.35% (21/1550) than voluntary donors 0.79% (43/5450). In case of anti-HCV, seropositivity was also higher among replacement donors 1.22% (19/1550) than voluntary donors 0.72% (39/5450).

The maximum seroprevalence of HBsAg and anti-HCV (1.56% & 1.21% respectively)was seen in the age group of 31-40 years. The minimum seroprevalence of both HBsAg and anti-HCV were seen among the age group of >51years (0.49% in both the cases) as depicted in fig.1.

Seroprevalence of HBsAg was maximum among male donors as compared to female donors (0.81% vs. 0.21%). None of the female donors were positive for anti-HCV but 0.88% of male donors were positive for anti-HCV.

As compared to unmarried donors, married donorshad maximum seroprevalence both in case of HBsAg (1.1% vs. 0.60%) and anti-HCV (1.03% vs. 0.48%).

Maximum seropositivity in case HBsAg (1.12%) was seen among donors educated uptointemediate level. In case of anti-HCV, seropositivity was highest among donors educated up to graduate level (0.91%).

Seropositivity was highest among first time donors in case of both HBsAg and anti-HCV (0.91% & 0.88% respectively) as compared to repeat donors (fig 2).

Skilled workers had maximum seroprevalence in both HBsAg and anti-HCV (2.19% &1.75% respectively).

The maximum seroprevalence of both HBsAg and anti-HCV (1.93% & 1.78%) was seen among blood donors from rural area as compared to urban donors that was statistically significant (table 1 & 2).

TABLE 1: DISTRIBUTION OF HBs Ag POSITIVE BLOOD DONORS BASED UPON AREA

Area	Voluntary			Replacement		
	Total	HBsAg +ve	%age	Total	HBsAg +ve	%age
Urban	3378	9	0.27%	1087	6	0.55
Rural	2072	34	1.64%	463	15	3.23%
Total	**5450**	**43**	**0.79%**	**1550**	**21**	**1.35%**
p value	**<0.001; Highly Significant**			**<0.001; Highly Significant**		

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TABLE 2: DISTRIBUTION OF ANTI HCV POSITIVE BLOOD DONORS BASED UPON AREA

Area	Voluntary			Replacement		
	Total	anti HCV +ve	%age	Total	anti HCV +ve	%age
Urban	3378	10	0.30%	1087	3	0.28%
Rural	2072	29	1.40%	463	16	3.46%
Total	**5450**	**39**	**0.72**	**1550**	**19**	**1.22**
p value	**<0.001; Highly Significant**			**<0.001; Highly Significant**		

DISCUSSION

The transfusion of blood is a life saving procedure and benefits millions of patients worldwide. Human beings are the only reservoir of blood borne viruses like HBV, HCV and are of concern because of their prolonged viremeia and latent or carrier state. Prevalence of HBV and HCV among healthy blood donors or replacement donors reflects the disease prevalence in the community. It also estimates the risk of chance of acquisition of these infections during blood transfusion. Serological testing of HBV and HCV is compulsory in blood banks routinely. In India testing blood for HBsAg and anti-HCV was made compulsory on 1999 and 2001 respectively[9].These tests are must for safe blood transfusion. Blood donors include the healthy adult population in the 18-60 year age group. But it is generally accepted that the evaluation of donors' blood for seropositivity of HBV and HCV gives an idea for the epidemiology of these infections in general population[10].

HBV and HCV infections are common serious complications of blood transfusion. Prevention of transfusion-transmitted infections in developed countries has been achieved by reducing unnecessary transfusions, using only regular voluntary donors, excluding donors with specific risk factors and systematic screening of all donated blood for infection. By contrast, in many developing countries none of these interventions is applied uniformly and the risk of transfusion-transmitted infection remains high[11].

HBV is one of the major public health problems. HBV infection is the tenth leading cause of death and HBV related hepatocellular carcinoma is fifth most frequent cancer worldwide. Approximately 30% of the world's population has serologic evidence of current or past infection with HBV. India lies in an intermediate HBVendemic zone and the number of HBV carriers is estimated to be 50 million, forming the second largest global pool of chronic HBV infections[12-14].

HBV prevalence in general population in India is 2% to 8% and 1% to 2% in blood donors, according to various studies. In developed countries like USA, the risk of HBV transmission through blood transfusion is 1: 63,000units transfused.[15] In southeast Asia Region, Sri Lanka has lowest HBsAg carrier rate of 0.9% in donor population[16] In the present study seroprevalence of HBsAg is 0.91%. An increasing incidence of HBV (2.6% in 2006, 2.67% in 2007 and 3.43% in 2008 and overall 2.9%) was noted in blood donors in Bhopal[17].Healthy voluntary first time blood donors in kolkota had 1.55% seropositivity[18]. Voluntary blood donors in Chandigarh had 0.66% seropositivity of HBV[19] Even the rural population of Ambajogai, India had very high prevalence of HBV (4.84%), a matter of concern[20]

The seroprevalence in replacement donors was higher compared to voluntary donors (1.35% vs. 0.79%) emphasizing the fact that donor recruitment is vital and voluntary donations should be encouraged.

Our study shows that rural residents had higher rates of HBsAg positivity than those in urban areas (1.94% vs. 0.34%) thatwere significant statistically. The highest rate of HBsAg positivity was among the age group of 31-40 years. Also males had higher rates of HBsAg positivity than did females (0.94% vs. 0.21%). Similar results were reported in a study in Pakistan in which the prevalence was 2.5% for HBsAg and among them majority of cases were males[8].

HCV infection is an evolving public health problem globally. This virus infects approximately 3% world's population, placing approximately 170 million people at risk of developing HCV-related chronic liver disease[21].

Prevalence of HCV is 0.5% to 1% and there are about 15 million HCV carriers in India[9].Prevalence of anti-HCV in blood donors in developed countries ranges from 0.4-2%[22].In USA, the risk estimate of HCV transmission is 1:103000 per donor exposure and with mini pool-NAT screening, the risk of HCV transmission will be as low as 1 in 2 million[15,23].In the present study seroprevalence of anti-HCV is 0.84%. The seroprevalence in replacement donors was high compared to voluntary donors (1.22% vs. o.72%).

The seroprevalence of anti-HCV was higher in rural donors as compared to urban donors (1.77% vs. 0.29%). Also males had considerably higher rates of anti-HCV positivity than did females. Similar results were reported in Egypt in a cross-sectional survey in Upper Egypt in which the prevalence of anti-HCV was higher among males than females[24].

In our study, the highest seroprevalence of both infections was found among manual workers, which may be due to their lower educational level and perhaps sharing and inconsistent use of clean shaving equipment. Our results are consistent with the findings of Darwish et al. among blood donors in Egypt, who found a higher rate co anti-HCV antibodies among manual workers[25]. In a study in Karachi, Pakistan seroprevalence of HBV and HCV infections among college going students is significantly lower (<3%) than 30% seroprevalence among paid donors and 7% among family/replacement donors[26].In our study also seroprevalence of HBsAg (1.35% vs. 0.79%) and HCV (1.22% vs. 0.72%) was higher among replacement donors as compared to voluntary donors.

Different Asian countries had reported seropositivity in blood donors. Prevalence of HBV and HCV in North Pakistan was 0.82% and 2.46% in voluntary remunerated blood donors[27]. Central Saudi Arabia had reported 1.5% and 0.4% HBV and HCV with a tendency to increase with increase of age[28]. In Bangladesh, 1.39% were found positive for HBV 0.024% were positive for anti-HCV in voluntary blood donors[29]. In Katmandu, Nepal, seroprevalence of HBV and HCV were observed to be 0.47% and 0.64% respectively[30].

Additional laboratory tests of interest including anti-hepatitis B core antigen, in any patient with HBsAg positivity and confirmatory testing for anti-HCV antibodies including HCV-RNA should be done in any anti-HCV positive patients in order to differentiate between

active and resolved infection. The presence of anti-HBc antibody is a lifelong marker of HBV infection, irrespective of whether a patient has recovered from or has an ongoing chronic infection[31-32]. This study recommends to perform confirmatory tests for both anti-HCV and HBsAg to confirm the rate of positive cases and cut-off values.

In conclusion our study raises serious concerns regarding the HBV and HCV prevalence and the safety of the blood supply in our country. The absence of HBsAg in blood of apparently healthy individuals may not be sufficient to ensure lack of circulating HBV. We also recommend nucleic acid testing(NAT) which as the ability to detect a disease at an earlier stage. It reduces window period, allowing early detection of infection hence reduces the chances of infection via transfusion. In case of HBV it reduces window period from 36 days to 20 days and in HCV from 65 days to 3 days[22].

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 including public awareness, educational and motivational programs, better donor recruitment, promoting voluntary donations, safe sexual practices,proper sterilization of instruments, proper disposal of contaminated material, inclusion of nucleic acid amplification test, antibody to HBcAg and other sensitive markers to be mandatory screening protocol, mass immunization programme including immunization of people at risk, particularly health care workers.

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