

# Viral Hepatitides among the Blood Donors in a Rural Based Hospital: A Five Year Study

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## ABSTRACT

**Background:** Hepatitis B virus (HBV) and Hepatitis C virus (HCV) are important transfusion-transmissible infections. This study was performed for the assessment of the prevalence of HBV and HCV sero positivity among the blood donors at a tertiary care hospital-based blood bank which is located in rural southern India.

**Study Design and Methods:** The blood donation records over a period of 5 years which ranged from 2006-2010 were reviewed retrospectively, for the prevalence and the yearly trends of HBV and HCV sero positivity.

**Results:** A total of 25,341 donations were received. The overall number of the Hb- sero-positivedonations was 233 and that for HCV was 55. The prevalence rates of 0.92% and 0.22% were noted for the hepatitis B surface antigen (HBsAg) and for HCV respectively. The sero positivity rate was higher in the replacement donors as compared to that in the voluntary donors.

**Conclusions:** Stringent measures need to be taken, including the dissemination of information, strict screening of blood, inclusion of the antibody to the hepatitis B core antigen and other sensitive markers for the screening protocol, and better donor recruitment.

**Key Words:** HBsAg, HCV, blood donors

## INTRODUCTION

Approximately 30% of the world's population or about 2 billion persons have serological evidence of either a current or past infection with HBV. Countries are classified on the basis of the endemicity of the hepatitis B virus (HBV) infection into high (8% or more) intermediate (2-1%) or low (less than 2%) incidence countries [1].

The HBV and the HCV infections are transfusion transmissible infections; hence, it is mandatory to test all blood and blood components for the presence of HBV and HCV [2]. Sero- surveys are one of the primary methods which can be used to determine the prevalence of HBV and HCV, as they give an idea about the prevalence of these diseases in the community and help in the creation of long-term strategies to improve the public health and to prevent spreading of the disease in the local population [2].

HBV is an enveloped DNA virus which belongs to the hepadnavirus family and HCV is an enveloped RNA virus which belongs to the flavivirus family [1]. Both the viruses have the following common characteristics (i) presence of these agents in different constituents of blood (ii) a prolonged incubation period for the development of clinical symptoms (iii) ability to cause asymptomatic infections (iv) prolonged persistence in donor blood, giving rise to a carrier or a latent state and (v) stability in the stored blood and the plasma fraction at 4°C or lower [1].

Although blood transfusion can be life-saving, there is an associated risk of an error in the entire process of the transfusion chain, right from the selection of the donors to the testing of patients and we are far from achieving a zero risk status [2]. Only continuous improvement, careful donor selection, proper selection of the sensitive screening tests, adequate quality control measures and effective inactivation procedures can ensure the elimination, or

at least reduction, of the risk of acquiring transfusion transmitted infections [2].

## MATERIALS AND METHODS

The present study was undertaken at Kolar, which is located in southeastern Karnataka, India. The population of the Kolar district is 2,523,406 and its population density is 307 sq.km, with a gender ratio of 970 females per 1000 males. The literacy rate is 73.14% in males and it is 52.81% in females. The Kolar district of Karnataka shares borders with the states of Andhra Pradesh and Tamil Nadu. 90% of the local population is involved in agriculture and animal husbandry.

Ours is a licenciated, 900 bedded, tertiary care, teaching hospital based blood bank, which is attached to a post graduate medical institute with the facilities for blood and blood component collection, preparation, storage and distribution. In addition to the routine hospital demand, our blood bank caters to the demand of the neighboring districts of Chikkaballapura, the Chittoor district of Andhra Pradesh and also the Hosur and the Krishnagiri districts of Tamil Nadu.

We reviewed 25,341 blood donor record over a period of five years, which ranged from January 2006 to December 2010. All the entries were double-checked by each author. The donors were carefully selected after a complete physical examination and after they satisfactorily answered the donor's questionnaire. The family members, friends or relatives of the patients were categorized as the replacement donors. The people who selflessly donated blood or participated in voluntary blood donation camps were classified as voluntary blood donors. Paid donors and known high-risk donors were excluded. An informed written consent was obtained from all the donors.

5ml of blood was collected aseptically from each donor into sterile test tubes and it was tested for the HBsAg and the anti-HCV antibodies. HbsAg and HCV screening was done by using the commercially available ELISA Kit (J-Mitra Co. India) as per the manufacturer's instructions. All the reactive samples were tested again by using the same ELISA kit, as well as a rapid test kit which was based on the principle of a one-step immunoassay (J-Mitra Co. India). Samples which showed a repeat test reactivity by both the methods were considered as positive and they were included for the calculation of the sero-prevalence. All those who turned out to be positive for HbsAg and HCV were subjected to a reconfirmation by testing them again twice on consecutive days. The Chi-square test was used for the statistical analysis of the results.

The blood samples which were still sero-positive were discarded. All the sero-positive donors were notified and counseled via telephone calls, e-mail, or letters and they were requested to come to our hospital or to attend a local physician or hospital for further medical evaluation and possible treatment.

## RESULTS

[Table/Fig-1] shows the annual distribution of the donor category and the gender distribution. Male voluntary donors were the main group of blood donors. [Table/Fig-2] shows the year wise distribution of the HbsAg and the HCV sero-positivity. The HbsAg sero-positivity remained stable, while there was a gradual increase in the HCV sero-positivity. [Table/Fig-3] shows the comparison of the HBsAg prevalence rate in different parts of India. Kolar showed a prevalence of 0.92%. [Table/Fig-4] shows the comparison of the HCV prevalence rate in England and Kolkata. Kolar showed a prevalence of 0.22%.

Year	Total donors	Replacement		Voluntary	
		Males	Females	Males	Females
2006	5037	1593	25	3366	53
2007	4493	1059	14	3293	127
2008	4915	585	08	4137	185
2009	5111	217	01	4673	220
2010	5785	100	90	5295	300
Total	25341	3554	138	20764	885

[Table/Fig-1]: Donor category and gender distribution of the blood donors (age-18-60 years)

Year	HBV donors	%	HCV donors	%
2006	30	0.59	4	0.07
2007	43	0.95	6	0.13
2008	45	0.91	9	0.18
2009	55	1.07	13	0.25
2010	60	1.03	23	0.39
Total	233		55	

[Table/Fig-2]: Annual Incidence of HBV & HCV Sero-positive donors

Place	Prevalence
Dehradun [13]	0.99%
Kolkata [14]	1.66%
Kanpur [15]	2.25%
Bangalore [16]	1.86%
Coastal Karnataka [17]	0.62%
Kolar	0.92%

[Table/Fig-3]: Comparison of HBsAg prevalence rate in different parts of India

Place	Prevalence
England [11]	0.16%
India (Kolkata) [14]	0.35%
India (Kolar)	0.22%

[Table/Fig-4]: Comparison of HCV prevalence rate in different parts of India

## DISCUSSION

Every blood transfusion carries a potential risk for transmissible diseases. This reflects the need and the importance of the mandatory screening for the above infectious markers in blood donations. The prevalence of infections among blood donors has been used as a surrogate marker for the prevalence of infections in the population at large. Although certain pitfalls like the exclusion of people below 18-years and over 60-years of age and the presence of a low number of female donors have been cited, it is still an important indicator of the disease burden [1]. The screening and the assessment of these not only alleviates the risk of transmission through infected blood products, but it also gives an idea about the prevalence rates of the infections in the community [1].

The blood transfusion services in India are primarily fragmented, disorganized and hospital based. The blood safety, as in other developing countries, remains an issue of major concern [1]. This issue is aggravated by the lack of a comprehensive and systematic screening of the donated blood and the predominance of replacement donors. According to a study, 1.5 million units of blood are transfused in India every year. However, as in other countries in the region, the demand far outstrips the supply [1].

India, with a carrier rate of 3 %, contributes nearly 10 % of the total HBV carriers in the world [1]. The number of HBsAg carriers in India is estimated to be over 40 million. Without any organized HBV prevention programme and with 25 million live births each year, nearly 1 million HBV infections are added to the HBV pool in India annually, thus contributing to its rapid expansion [1].

Several epidemiological studies on hepatitis B and C have been conducted, mostly in blood banks, and some of them have analyzed specific subpopulations which are usually at a higher risk for blood-borne or sexually transmitted infections, such as patients who are infected with HIV, sex workers, dialysis patients, intravenous drug users, prisoners, haemophiliacs and populations in hyper endemic regions [2]. In India, both these infections are common with a considerable variation, because of the variability in its ethnicity and geography. Despite the clinical and epidemiological importance and the impact of these diseases, no nationwide study on hepatitis B and C has been conducted [3].

In a vast country like India, a survey on blood transmissible diseases in the country as a whole, is very difficult. Individual epidemiological surveys of each state may help us to understand the seriousness of the problem and the changing trends [1]. Among the blood transmissible diseases, hepatitis B and C, HIV, syphilis and malaria are the major public health problems in the developing countries. In India, hepatitis B accounts for 15-30 % of the cases of acute hepatitis and 70 % cases of chronic hepatitis, while HCV is an infrequent cause of acute icteric hepatitis, though it is responsible for most of the cases of post transfusion hepatitis. Moreover, these chronically infected patients serve as a reservoir for continuing the HBV transmission [2].

Ideally, if 2% of the population donates blood, it will be sufficient to meet the needs. India, with a population of over a billion, has

a meager availability of 2.5 million blood units against an annual requirement of approximately 6 million units [2]. Following the high incidence of hepatitis B among the paid donors, the Honorable Supreme Court of India, in 1998, banned the payment of money to the blood donors, leading to further shortage of blood units in India, because of the lack of a public initiative which was related to the general illiteracy, poor knowledge of the blood donation, little motivation and religious beliefs and misconceptions [1].

The HBV prevalence in the general population in India is 2% to 8% and it is 1% to 2% in the blood donors, according to various studies. HBV infection is the 10th leading cause of death and HBV-related hepatocellular carcinoma is the fifth most frequent cancer which has been reported worldwide [2]. Approximately 30% of the world's population has a serologic evidence of a current or past infection with HBV. India lies in an intermediate HBV endemicity zone and the number of HBV carriers in India is estimated to be 50 million, thus giving it the status of being the second largest global pool of chronic HBV infections [1].

In Delhi, Panda et al reported an HBsAg prevalence rate of 1.13% [3] amongst blood donors, while Pahuja et al the reported a prevalence of 2.23% [4]. Garg et al reported a prevalence rate of 3.44% amongst the blood donors in western India [5]. Chatteraj et al reported a 0.99% sero-prevalence of HbsAg amongst the blood donors at Dehradun [6]. Bhattacharya et al reported a 1.66% sero-prevalence of HbsAg amongst the blood donors of Kolkatta [7], while Behal R et al, reported a 2.25% of sero-prevalence of HbsAg amongst the blood donors at Kanpur [8]. Srikrishna et al, observed a 1.86% sero-prevalence rate of HbsAg amongst blood donors at Bangalore [9], while Karandeep Singh et al, observed a 0.62% sero-prevalence rate of HbsAg amongst the blood donors in coastal Karnataka [10]. In our study, we observed a sero-prevalence rate of 0.88% among the blood donors in the district of Kolar.

The global prevalence rate for the HCV sero positivity is 3.1% [11]. The highest prevalence rate is in Africa (5.3%) and it is the lowest in Europe (0.03%). This virus infects approximately 3% of the world population, thus placing approximately 170 million people at a risk of developing HCV-related chronic liver disease [11]. In India, the prevalence of the HCV infection, as a cause of acute viral hepatitis, has been reported to vary between 0-21 % and it has been found to be responsible for 14-26 % of the chronic liver diseases [12].

The magnitude of the HCV infection amongst the patients of chronic liver disease is likely to increase in future, since the blood banks in India have only recently introduced the policy of anti-HCV screening. Hence, all those individuals who had been exposed before this are likely to develop the disease in the next 15-30 years. No vaccine has yet been developed against hepatitis C because of its large and frequent genetic variations [13]. The screening of blood for HCV should be performed by using a highly sensitive and specific HCV antibody immunoassay or a combination HCV antigen-antibody immunoassay. The assay should be capable of detecting the genotypes which are specific to the country or region [14].

The sero-prevalence of HCV in England was 0.16% [15] and in Kolkata, it was 0.35% [15] respectively. The global sero-prevalence of HCV among the blood donors varies from 0.4% to 19.2% [15]. In various studies which were performed at Delhi, the prevalence of HCV in the blood donors was reported to range from 0.66% to 2.5% [15]. In our study, the sero-prevalence of the HCV antibody amongst the blood donors was 0.21%.

Stringent measures need to be taken on an urgent basis, which include the dissemination of information, strict screening of blood and blood products, inclusion of the nucleic acid amplification test, the antibody to the hepatitis B core antigen and other sensitive markers to the mandatory voluntary donations, safer sexual practices, proper sterilization of the instruments, proper disposal of contaminated material and immunization of the people who are at risk, particularly the health care workers [16].

The problem of a chronic infection with HCV may be greater than it has been generally recognized. While effective vaccines currently exist for HBV, a fully protective HCV vaccine is not yet available and the current treatment methods for the HCV infection are not highly effective or globally applicable [17].

## CONCLUSION

The magnitude of the risk of the hepatitis infection via donated blood appears to vary with the demographic characteristic of the donor population. A higher incidence of the sero-prevalence was noted in the donor population of the reproductive age group, who had a low socio-economic status [16].

'Blood saves lives' was the World health Organization (WHO) theme for the 2000 AD [1]. A universal access to safe and adequate blood is the essence of good blood transfusion services. An adequate quality blood can be ensured by promoting voluntary blood donation and it involves the identification, recruitment and the retention of voluntary blood donors (VBSs).

Voluntary blood donors provide the safest blood, followed by the replacement donors who are young, healthy and highly literate and those who have donated blood on more than 3 occasions [16]. Such replacement donors could be sensitized, motivated and recruited as the regular voluntary donors. Our current findings provide an opportunity to the hospital based blood banks to improve blood safety and to reduce the wastage of contaminated blood by targeting safe replacement donors for recruitment as regular voluntary donors. These measures will also be in accordance with the W.H.O recommendations, to have voluntary, non remunerated blood donors as a source of a regular and safe blood supply [17].

There is a need to collect data at the national, state, and the district levels for the evaluation and supervision of the public health programmes, as the existing systems are not credible enough for monitoring their effectiveness. The epidemiology of viral hepatitis is shifting and it presents new challenges which require support from governmental, academic, and community based organizations [17].

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