



FREQUENCY AND ANNUAL TREND OF HBSAG SEROREACTIVITY AMONG WHOLE BLOOD DONORS AT A REGIONAL BLOOD TRANSFUSION CENTRE

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ABSTRACT **Introduction:** Transmission of hepatitis B through blood transfusion is a documented and dreaded complication. Transfusion Services exclude potential infective donors through thorough screening of blood donors. This study attempts to establish the trend of seropositivity for Hepatitis B Surface antigen among blood donors at Dept of Transfusion Medicine, Govt. Medical College, Thiruvananthapuram.

Materials & Methods: 155275 blood donors who donated whole blood over a span of 5 years from 2012 January to 2016 December were screened with ELISA for Hepatitis B Surface antigen. Percentage of seroreactivity was noted. Trend was statistically analysed by Chi square test.

Result: 1141 (0.92%) samples were found to be seroreactive. Yearwise prevalences remained <1% (ranging from 0.96% in 2012 to 0.85% in 2016). There was a statistically significant decreasing trend.

Conclusion: Seroprevalence of Hepatitis B surface Antigen is approximately 1% and it is steadily decreasing although in small quantities. Transfusion services should aim to bring it down to near zero.

KEYWORDS :

Introduction

Hepatitis B virus (HBV) remains a major risk of transfusion-transmitted infection, main reasons being attributed to the existence of pre-seroconversion window period, infection with immunovariant varieties of viruses, and with occult carriage of HBV infection¹ which may escape detection.

HBV infection results in substantial human morbidity and mortality, predominantly through the consequences of chronic infection. Prevalence of individuals chronically infected with HBV have ranged from 240 million² to 350 million³ with more than two billion humans globally ever having been infected. Majority of deaths due to HBV infection are attributable to liver cancer and cirrhosis⁴. As a result, HBV infection was considered as an important cause of human mortality

Before 1970, approximately 6% of multi-transfused recipients acquired transfusion-transmitted HBV⁵. Over the last four decades, the risk of transfusion-transmitted hepatitis B virus has been steadily reduced. The residual risk of HBV transfusion transmission is mainly related to blood donations negative for HBsAg that have been collected either during the pre-seroconversion 'window period' defined as the time between infection and detection of a viral antigen or antibody marker, or during the late stages of infection.

After the ill effects of professional blood donation became clear and it was legally banned in India in 1998, many blood centers refocused on methods to recruit only voluntary donors as the main source of blood supply. Moreover efficient counselling measures to eliminate high risk donors have been developed enhancing the additional level of safety. Yet phasing out and abolishing replacement donation totally is one of the biggest challenges faced by Indian blood banks.

We examined the serological profile of 155275 donors donating blood over a span of 5 years and analysed the trend in seroreactivity over the years. This may be helpful in analysing the efficiency of donor screening and detection and modifying strategies accordingly. It also may give us a rough estimate of prevalence in asymptomatic adult population in south Kerala.

Materials & Methods

155275 subjects who donated whole blood, from January 2012 to December 2016 at Govt. Medical College, Trivandrum were included in the present study. A thorough clinical history, medical examination and selection of donors were done according to Standard Operating Procedures. Demographic data was recorded. 5 ml anticoagulated blood collected at the time of blood donation was used for testing. All the donors were tested with a third generation ELISA (Hepa Lisa, M/s Transasia Biomedicals) for HBSAg. Acceptance criteria which were laid down by the manufacturer for the absorbance of the reagent

blank as well as for the mean absorbance of the positive and negative controls which were provided with the test kits were strictly followed. The cut off value was calculated as per manufacturer's directions for reporting the positive and the negative results. Apart from manufacturer control, known in house positive and negative samples were used randomly as the external controls in each screening. The samples which were found seroreactive were repeated in duplication by ELISA and those found reactive in at least one of the repeated tests were taken as seroreactive.

Data was entered in excel on a daily basis and analysed with SPSS. Frequencies were reported as percentages. Chi-squared statistics for trend was used to estimate whether a significant difference existed between the yearly prevalence of HBSAg

Results

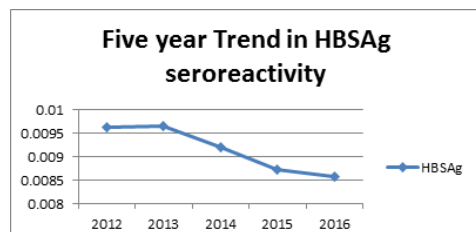
A total of 155275 blood samples were analysed for presence of HBSAg and 1141 samples were found to be seroreactive. Yearwise prevalences remained <1% (ranging from 0.96% in 2012 to 0.85% in 2016). to and overall prevalence during 5 years was 0.92% as shown in table 1.

Table 1. Frequency of seroreactivity for HBSAg in whole blood donors from 2012 to 2016

Year	Total no of Whole blood donations	HBSAg seroreactivity	HBSAg seroreactivity (%)
2012	28194	271	0.96%
2013	32423	313	0.96%
2014	32271	297	0.92%
2015	31367	274	0.87%
2016	31020	266	0.85%
Total	155275	1421	0.92%

To study the trend of during the study period Chi square for trend was employed. Trend of HBSAg positivity is depicted in figure 1. A steady linear decreasing trend was observed which was statistically significant. $P < .001$

Figure 1: Trend of seroreactivity in asymptomatic donors over 5 years



Discussion

HBsAg tests remain the first-line of blood screening for HBV. Current HBsAg screening assays are enzyme immunoassays (EIAs), including enzyme-linked immunosorbent assays (ELISAs), and chemiluminescence immunoassays (CLIAs). These different assays have sensitivity ranging between <0.1 and 0.62 ng of HBsAg per mL (1 ng/mL corresponds to approximately 2 IU/mL)⁶⁷

The increasing significance of hepatitis B virus is effect of its impact on public health which in turn emphasizes the importance of prevalence studies of this disease. Blood Transfusion Services all over the world strive to control this disease thro enable advance technologies in all the stages of donor selection and screening. Although blood donor population is asymptomatic and healthy subsection of general population, any infectious marker in them may not be exactly reflective of the overall prevalence in general.This is because blood donors are selected using a well validated and comprehensive questionnaire which excludes those having known risk factors of transfusion transmitted hepatitis.

There have been various attempts to describe the trends in seroprevalence of HbSAg in asymptomatic blood donor population. Prevalence reported in india in recent years varies widely in different geographical parts. Considering only reports published in or after 2016 in India, very similar prevalences of 1.56,1.6 ,1.7 AND 1.8 were observed from provinces like Kashmir⁸,Rajasthan⁹,Uttarpradesh¹⁰ and Mumbai¹¹ respectively. Lower prevalence of 0.5% was observed from Tumkur¹² in South India but in a fewer number of study subjects. Comparing with international data,The pooled prevalence of HBsAg in blood donors of both EMRO and middle eastern (E and M) countries was 2.03%¹³. African countries report a much higher rates where a prevalence of around 10%¹⁴ contrast to a very low prevalence of 0.3% in Italy¹⁵ also is reported.

While observing the trend in prevalence of HBSAg over 5 years, we found a slight but steady decreasing trend which was statistically significant(Chi square value 61,P<.001). Various other authors has also observed a decreasing trend in hepatitis B^{16,17,18} and also in Hepatitis C^{19,20,21}. This decrease can be attributable to increase of public knowledge on transfusion-transmitted infections and improving of the safety measures employed in recent years.Notable changes which occurred in transfusion services past few years are mandatory screening all blood donors high risk behaviour prior to donation and application of strict pretested questionnaire to potential donors. Application of set standards in questionnaire as well as utilisation of counsellors qualified in medical sociology and allied sciences have led to an effective donor selection program.There were many programmes for validation of counselling procedures and training across the country,. Recent advances in Information technology has helped to maintain a data registry of blood donors with history of positive screening tests thereby avoiding their repeat donation.These factors also imply that prevalence in blood donors may not replicate the prevalence in general adult population.

Conclusion

Seroprevalence of Hepatitis B surface antigen in asymptomatic blood donors after all screening measures approaches 1% in the centre. Exploring a more stringent donor selection and enhancing detection hopefully may decrease the threat of transfusion transmitted HBV Further.

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