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Research Article

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A study in the seroprevalence of hepatitis B core antibody and other transfusion transmitted infections in blood donors

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ABSTRACT

Background: Hepatitis B virus (HBV) infection can lead to acute or chronic hepatitis. There is a phase during which the HBsAg cannot be detected in the blood, although hepatitis B infection is present. During this window period, detection of the antibody to the hepatitis B core antigen (anti-HBc) serves as a useful serological marker for hepatitis B infection. This study was undertaken to detect the Hepatitis B core antibody and other transfusion transmitted infections (HBsAg, HIV, HCV, Malaria and Syphilis) among healthy blood donors in the Kancheepuram district, TamilNadu and its impact in our blood transfusion services.

Methods: A total of 6954 blood donors were selected. 5 ml of blood from each donor was collected from the collection bag into a sterile capped tube. It was then centrifuged and the plasma was sepa-rated and stored as two aliquots at -70°C till further use. The screening for the Hepatitis B core antibody (anti-HBc) was done by a competitive immunoassay technique with ortho clinical diagnostics Anti-HBc (IgM and IgG) reagent kit and were run in a fully automated Vitros Immunodiagnostics system.

Results: Of the total 6954 donor blood samples which were tested, 713 samples (10.2%) were found to be positive for anti-HBc (IgM and IgG) and 93 samples (1.3%) were found to be positive for HBsAg.

Conclusions: Our study helped in determining the prevalence of hepatitis B core antibody and its subsequent detrimental effect on the blood donor population due to its high prevalence rate.

Keywords: HBsAg, HIV, HCV, Vitros immunodiagnostics system

INTRODUCTION

Hepatitis B virus (HBV) infection can lead to acute or chronic hepatitis. The first clue in unraveling this infection was the discovery of an enigmatic serum protein named Australian antigen 50 years ago by Baruch Blumberg. Some years later this was recognized to be the HBV surface antigen (HBsAg). Detection of HBsAg allowed for the first time screening of in apparently infected blood donors for a dangerous pathogen. I

In India, the prevalence of the Hepatitis B infection is 4% in the general population, which means that 40 million people are infected with HBV in our country. The prevalence of the HBV infection in the voluntary blood donors is 1-3%.²

Presently, screening for HBsAg, HIV antibody, HCV antibody, Malaria and Syphilis are the only mandatory screening tests in blood banks in India as per The Drugs and Cosmetics Act. Screening of blood for the detection of HBsAg, however, does not rule out the risk of

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transmission of hepatitis B totally, because during the serological response of the host to infection, there is a phase during which the HBsAg cannot be detected in the blood, although hepatitis B infection is present. This phase is called as the core window period. During this window period, detection of the antibody to the hepatitis B core antigen (anti-HBc) serves as a useful serological marker for hepatitis B infection.³

This study was undertaken to detect the Hepatitis B core antibody and other transfusion transmitted infections (HBsAg, HIV antibody, HCV antibody, Malaria and Syphilis) among healthy blood donors in the Kancheepuram district, Tamilnadu and its impact in our blood transfusion services.

METHODS

This study was conducted from September 2012 to April 2014 in the Department of Transfusion Medicine, S.R.M Medical College and Hospital, S.R.M University, Kancheepuram, India. All donors (both replacement and voluntary) fulfilling the general criteria for blood donation were included in the study. Donors who did not fulfill these criteria were deferred from donating blood and hence excluded from the study. Consent for blood donation and infectious maker testing was obtained at the time of donor selection. A total of 6954 blood donors were selected. 5 ml of blood from each donor was collected from the collection bag into a sterile capped tube. It was then centrifuged and the plasma was separated and stored as two aliquots at -70°C till further use. The screening for the Hepatitis B core antibody (anti-HBc) was done by a competitive immunoassay technique with ortho clinical diagnostics anti-HBc (IgM and IgG) reagent kit and were run in a fully automated Vitros Immunodiagnostics system. The screening for the Hepatitis B surface antigen was done by an immunometric immunoassay technique with ortho clinical diagnostics HBsAg ES reagent kit and were run in the fully automated vitros immunodiagnostics system. The screening for malaria (Alere trueline) and syphilis (SD Syphilis 3.0) were done by a rapid card test (Bio standard Diagnostics). The screening for HIV antibody and HCV antibody was done in ortho clinical diagnostics reagent kit and were run in the vitros Immunodiagnostics automated system.

RESULTS

Among the total 6954 donors in the study, 6868 (98.7%) were males and 86 (1.2%) were females. Of the total 6954 donor blood samples which were tested, 713 samples (10.2%) were found to be positive for anti-HBc (IgM and IgG) and 93 samples (1.3%) were found to be positive for HBsAg. Out of these 93 HBsAg positive samples, 89 were also positive for the core antibody and 4 only were negative for core antibody. 624 samples were found to be positive for the core antibody alone and all these were negative for HBsAg (Table 1). The prevalence

of all the other transfusion transmitted infections were HIV antibody (0.07%), Hepatitis B surface antigen(1.3%), Hepatitis C antibody(0.7%), Malaria (0.02%) and Syphilis (0.02%)in our blood donors (Table 2).

Table 1: Comparison of anti HBC and HBSAG in donors.

HBs Ag	Anti HBc	No. of Donors	Percentage
Positive	Postive	89	1.28
Positive	Negative	4	0.06
Negative	Positive	624	8.97

Table 2: Prevalence of transfusion transmitted infections (TTIS).

TTI s	Prevalence (%)
Hepatitis B	1.3
HIV	0.07
Hepatitis C	0.7
Syphilis	0.02
Malaria	0.02

Table 3: Prevalence of hepatitis B core antibody in various studies.

Anti HBc (Reference)	Region	Positive donors (percentage)
Present study	Kancheepuram (Tamilnadu)	10.2
Dhawan et al ⁴	Chandigarh	8.4
Bhattacharya et al ⁵	Kolkata	18.3
Makroo et al ⁹	New delhi	10.2

Table 4: Prevalence of hepatitis B surface antigen in various studies.

HBsAg (reference)	Region	Positive donors (%)
Present study	Kancheepuram	1.3
Singh ⁷	Coastal Karnataka	0.62
Gagandeep ⁸	Chandigarh	1.7
Makroo ⁹	New Delhi	1.8

DISCUSSION

In our study the prevalence of the Hepatits B core antibody (anti-HBc) among the blood donors was 10.2 %. While Dhawan et al had a prevalence of 8.4 % done at Chandigarh, studies conducted by Bhattarcharya et al at Kolkata had a prevalence of 18.3 % respectively. This shows the prevalence varies depending upon the region within India (Table 3).

We had a prevalence of 1.3 % for blood donors positive for Hepatitis B surface antigen. This was low when compared to the prevalence of Hepatitis B done at Chennai by Maheswari et al (2.18%) nearby to our study region.⁶ Studies conducted by other authors on the Hepatitis B prevalence varied depending upon the region (Table 4).^{7,8}

The prevalence of all the transfusion transmitted infections (HIV antibody, Hepatitis B surface antigen, Hepatitis C antibody, Malaria and Syphilis) in our blood donors is only 2.1%. These are the mandatory infectious screening tests to be screened in blood donors as per the Drug and Cosmetics Act. But our prevalence of blood donors with only positivity in hepatitis core antibody alone is around 9%. This amounts to a significant number of Hepatitis B core antibody positive blood bags to be discarded in our blood bank. This puts an additional pressure on the blood bank to maintain an adequate blood supply. There are also other issues whether the core antibody reactive donors should be informed of his positive status. Studies conducted by Makroo et al showed 99.85% of anti-HBc positive donors were negative for HBsAg and HBV DNA.9

Study done by Sawke reported that as India has high prevalence of anti-HBc, screening of donor blood for total anti-HBc is not practical and should not be used as a criterion to discard blood. Screening for IgM- anti- HBc of blood units negative for HBsAg, on the other hand, could identify potentially infectious units. ¹⁰ Margaret et al recommended the inclusion of anti-HBc IgM in routine screening of blood donors in countries where DNA testing is not done. ¹¹ Allain has recommended that the use of anti-HBc screening of blood donors be restricted to areas where HBV seroprevalence is relatively low (< 2% anti-HBc reactivity) while Laperche concluded that HBV DNA screening would be more effective in countries with high or medium endemicity, and where anti-HBc testing is not routinely done. ^{12,13}

El-Sherif et al have proposed a policy of testing blood donors for anti-HBc in addition to HBsAg and those found positive for anti-HBc can be tested for HBV DNA testing. This approach would be less expensive, would reduce the risk of transfusion-transmitted HBV infection, and decrease the rejection rate of the precious units of collected blood positive for anti-HBc only. ¹⁴ Testing for anti-HBc for blood donors still remains an issue across the globe especially in a country like India where the prevalence of Hepatitis B core antibody is high.

CONCLUSION

Our study helped in determining the prevalence of hepatitis B core antiboby and its subsequent detrimental effect on the blood donor population due to its high prevalence rate. However anti-HBc can be used as a screening test in addition to HBsAg testing in areas of low endemicity of Hepatitis B prevalence.

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