ISSN 2321 – 7359 EISSN 2321 – 7367

discovery Cover the uncovered

Medical Science

Seroprevalence of hepatitis B virus markers in patients attending to a tertiary care hospital in Kanchipuram, India

Sandhya BK[1*], Apurba SS[2], Senthamarai S[3], Sivasankari S[4], Kumudavathi MS[5], Anitha C[6], Amshavathani SK[7]

1. Assistant Professor, Dept. of Microbiology, Meenakshi Medical College, Kanchipuram,Tamilnadu, India
2. Assistant Professor, Dept. of Microbiology, Meenakshi Medical College, Kanchipuram,Tamilnadu, India
3. Associate Professor, Dept. of Microbiology, Meenakshi Medical College, Kanchipuram,Tamilnadu, India
4. Associate Professor, Dept. of Microbiology, Meenakshi Medical College, Kanchipuram,Tamilnadu, India
5. Tutor, Dept. of Microbiology, Meenakshi Medical College, Kanchipuram,Tamilnadu, India
6. Tutor, Dept. of Microbiology, Meenakshi Medical College, Kanchipuram,Tamilnadu, India
7. HOD & Professor, Dept. of Microbiology, Meenakshi Medical College, Kanchipuram,Tamilnadu, India

[*]*Corresponding author:* Assistant Professor, Dept. of Microbiology, Meenakshi Medical College, Kanchipuram,Tamilnadu, India.. Mail: sandhyabhatk@gmail.com, Mobile No: (+91)9444327316

Received 13 September; accepted 21 October; published online 05 November 2013

ABSTACT

Introduction: Hepatitis B virus (HBV) infection is a global public health problem. It is the most common cause of chronic liver disease, including cirrhosis of the liver and hepatocellular carcinoma worldwide. Considering this disease burden caused by HBV infection, this study was undertaken to estimate the seroprevalence rate of various HBV markers in our tertiary care hospital. **Materials & Methods:** A total of 4522 patients attending to a tertiary care hospital were included in the study. Serum samples were screened for various HBV sero-markers by ELISA and Rapid immunochromatographic methods. **Results & Analysis:** Out of 4522 patients, 120 were positive for HBsAg. Overall prevalence of positive HBsAg was 2.56%; in males 4.68% and in females 1.56%. Among 4402 HBsAg negative patients, anti-HBs was positive for 1277 (29%) of patients. Maximum numbers of HBs Ag positive patients were young adults belonging to age group between 18 to 30 years of age. Among 120 HBs Ag positive patients, the prevalence of the hepatitis B e antigen was 1.66%, prevalence of the antibody to HBeAg was 5% and prevalence of the antibody to the hepatitis B core antigen was 13.3%. **Conclusion:** Using various serological markers will help in the diagnosis of accurate stage of HBV infection and facilitates adequate management. Compulsory childhood immunization is required to control the HBV infection rate and Complications.

Key Words: HBV infection, ELISA, Rapid Immunochromatographic kits, Vaccination

Abbreviations Used: Hepatitis B virus –HBV; Hepatitis B surface antigen –HbsAg; Hepatitis B surface antibody -anti-HBs; Hepatitis B core antigen – HbcAg; Hepatitis B core antibody-anti-HBc; Hepatitis B envelope antigen-HBeAg; Hepatitis B envelope antibody- anti-HBe

1. INTRODUCTION

Hepatitis B virus (HBV) infection with its associated sequel is a disease of major public health importance, being the 10th leading cause of death globally (Japhet et al. 2011). Approximately 2 billion people infected worldwide, more than 350 million are chronic carriers of HBV (Japhet et al. 2011 & Schmidt et al. 2006). Approximately 15-40% of infected patients will develop complications such as liver cirrhosis, liver failure or hepatocellular carcinoma (HCC) (Lok, 2002). The serological markers of Hepatitis B virus are hepatitis B surface antigen (HBsAg), hepatitis B surface antibody (anti-HBs), hepatitis B core antigen (HBcAg), hepatitis B core antibody [anti-HBc (IgM and IgG)], hepatitis B envelope antigen (HBeAg), hepatitis B envelope antibody (anti-HBe), and hepatitis B viral DNA (HBV DNA); these serological markers play an important role in diagnosis of the infection and to determine the severity of the infection (Gitlin, 1997). First serological marker to appear in the blood following HBV infection is the HBV DNA, followed by HBsAg, the DNA polymerase and HBeAg. Following to appearance of the antigens, antibodies to the hepatitis B antigens (HBcAb, HBeAb and HBsAb) start to appear in patients' blood (Davaalkham et al. 2007 & Chisari et al. 1995). The global epidemiological scenario of HBV infection has been changing rapidly over the last two decades due to an effective immunization programme initiated by the World Health Organization (Wang et al. 2011). The average estimated carrier rate of hepatitis B virus (HBV) in India is 4%, with a total pool of approximately 36 million carriers (Tandon, et al. 1996).

2. SCOPE OF THE STUDY

Considering the burden of carriers in our country we have undertaken this study to estimate the seroprevalence rate of various HBV markers in our tertiary care hospital.

2.1. Materials

A cross-sectional sero-survey was conducted among a total of 4522 patients (both males & females) attending to a tertiary care hospital (both out patients and in patients were included). Study was conducted from June 2011 to December 2012, for duration of one and a half years. Only adult patients (aged > or =18 years) were included in the study; children were not included. 1581 were male patients and 2941 were female patients.

Sandhya et al.
Seroprevalence of hepatitis b virus markers in patients attending to a tertiary care hospital in Kanchipuram, India,
Medical Science, 2013, 3(7), 17-19,
http://www.discoveryjournals.com/medicalscience.htm

© 2013 Discovery Publication. All Rights Reserved

2.2. Methodology

Demographic, behavioral information and clinical history were taken in detail from all 4522 patirnts. 5 ml of blood samples was taken aseptically from all patients in sterile vacutainers, after taking informed oral consent. All 4522 serum samples were tested for presence of HBsAg by using ELISA kits (HEPALISA from J. Mitra & Co. Pvt. Ltd). HEPALISA is a solid phase enzyme linked immunosorbent assay based on the "Direct Sandwich" principle. Test was performed using serum samples according to manufacturer literature guidelines provided along with the HEPALISA kits. Hepatitis B surface antibody (anti-HBs) was tested for all 4522 patients using “Rapid Immunochromatographic Assay kit for the detection of HBsAb in human serum” (Insight device / HBsAb by Tulip Diagnostics). Out of this 4522 serum samples, 120 serum samples were positive for HBsAg and were further subjected to various other hepatitis B viral serological markers. Hepatitis B core antibody [anti-HBc (IgM and IgG)] was tested by using Rapid Immunochromatographic Assay kit for the detection of HBcAb in human serum (Insight device / HBcAb by Tulip Diagnostics), hepatitis B envelope antigen (HBeAg) by using Rapid Immunochromatographic Assay kit for the detection of HBeAg in human serum (Insight device / HBeAg by Tulip Diagnostics) and hepatitis B envelope antibody by using Rapid Immunochromatographic Assay kit for the detection of HBeAb in human serum (Insight device / HBeAb by Tulip Diagnostics). All the above rapid immunochromatographic assays were tested according to the procedure given in the kit literature and the results were also interpreted based on the kit literature guidelines. The test result was considered invalid if no band appears at the Control Region (C). In such cases, test was repeated with a new Insight device (Tulip Diagnostics, 2011).

3. RESULTS

A total of 4522 patients were included in the study. Out of 4522 patients, 120 were positive for HBsAg in the serum samples tested.

3.1. Sex Distribution

Overall prevalence of positive HBsAg was 2.56% (120 out of 4522); in males 4.68% (74 out of 1581) and in females 1.56% (46 out of 2941). Lower prevalence rate was observed among female patients, when compared to male patients.

3.2. Age Distribution

Maximum number of HBs Ag positive patients were young adults belonging to age group between 18 to 30 years of age; 82 positive patients out of 120 (68.22%) were young adults. Among 4402 HBsAg negative patients, anti-HBs was positive for 1277 (29%) of patients. Among 120 HBs Ag positive patients, the prevalence of the hepatitis B e antigen (HBeAg) was 1.66% (2 out of 120), prevalence of the antibody to HBeAg (anti-HBe) was 5% (6 out of 120), and prevalence of the antibody to the hepatitis B core antigen (anti-HBc) was 13.3% (16 out of 120).

3.3. Risk Factor Distribution

Considering the multivariate logistic parameters like gender, clinical history, HBs Ag positivity rate was significantly found more among male gender, chronic smokers, alcoholics and patients with poor sleep pattern. These risk factors were not much observed among HBs Ag negative patients.

4. DISCUSSION

Hepatitis B virus infection (HBV) is a global public health problem (Lee, 1997). At least 15-25% of chronically HBV infected people will die due to liver disease caused by HBV and this constitutes nearly one million people each year (Lok et al. 2001). An effective vaccine is available for over two decades and has brought about remarkable changes in the global epidemiology of HBV infection. The prevalence rate of HBV infection in India is somewhere in between, with nearly 3-4% of the population infected by the virus, and chronic hepatitis B constituting more than 50% of the chronic hepatitis cases in the country (Chowdhury, 2004). Absence of a compulsory national immunization programme may be one of the leading causes for this disease burden in India. Hence, HBV epidemiology in India becomes relevant not only nationally, but also internationally, as there is chance for increase in the infection rate. Overall prevalence rate of HBV infection observed in our study was 2.56%, which is matching with level of national seroepidemiological survey rate (Tandon et al. 1996, Chowdhury et al. 2001 & Amarapurkar, 2007). According to the study done by Singh et al., (2009), HBsAg prevalence rate in south India is 2-4%.

Males (4.68%) were found to be more infected with hepatitis B virus, when compared to females (1.56%). Male gender preponderance was observed in our study, which was consistent with many other sero-epidemiological studies done by Wang et al., (2011) and Adoga et al., (2010). Although this did not reach statistical significance, implying that the difference might be due to chance. No concrete explanations can be given for the higher vulnerability of males to the HBV infection than females. Maximum number of HBs Ag positive patients belongs to 18-30 years age group, which is also consistent with many other studies (Wang et al. 2011, Davaalkham et al. 2007 & Singh et al. 2009). There is peak prevalence after the second decade of life (Amarapurkar, 2007). Independent predictors for chronic HBV infection were smoking; poor sleep quality; occupation as laborers; male gender; family history of HBV infection; no history of vaccination; and older age (Zhang et al. 2011). These risk factors were commonly observed among HBs Ag positive patients than in negative patients in our study also. Anti-HBs was positive for 1279 (29.5%) patients, which indicates that these patients are either infected with HBV or have been vaccinated by HBV vaccine in the past (Wang et al. 2011, Davaalkham et al. 2007 & Zhang et al. 2011). Out of 1279 anti-HBs positive patients only 2 patients were also positive for HBs Ag; hence remaining 1277 patients were probably vaccinated in the past.

The prevalence of HBeAg was 1.66% (2 out of 120). This indicates that these two patients were highly infective; as presence of HBe Ag indicates active intra-hepatic viral replication (Japhet, et al. 2011). Prevalence of anti-HBe was 5% (6 out of 120), which indicates these patients may be recovering from acute HBV infection. Disappearance of HBe Ag is usually followed by the appearance of anti-HBe (http://www.cdc.gov/hepatitis/hbv). Prevalence of the antibody to anti-HBc was 13.3% (16 out of 120).This positive patients were positive for combined (IgG & IgM) anti-HBc. As separate estimation of IgG & IgM anti-HBc was not done, it is difficult to conclude whether they were acute or chronic cases of HBV infection (http://www.cdc.gov/hepatitis/hbv). Using various serological markers will help in the accurate stage of HBV infection; facilitates adequate management. Existence of risk factors indicates the need for meta-analysis in different geographical areas to get adequate information about transmission routes and surveillance of hepatitis B infection.

5. LIMITATIONS OF THE STUDY

All 4522 patients were not screened by all serological markers due to financial constrains. Estimation of serological markers by ELISA is more sensitive than rapid tests. But Insight device, by Tulip diagnostics are quality controlled by various other sero-surveys.

6. CONCLUSION

Based on the reports obtained by various sero-epidemiological studies, it is likely that an effective childhood immunization programme will reduce the burden of HBV infection in this country. As HBV infection is vaccine preventable, complications due to chronic HBV infection such as cirrhosis, liver cancer can be totally prevented by compulsory immunization programmes and good awareness about the availability of effective vaccine. All high risk groups should be compulsory vaccinated, blood samples should be effectively screened before transfusion.

Sandhya et al.
Seroprevalence of hepatitis b virus markers in patients attending to a tertiary care hospital in Kanchipuram, India,
Medical Science, 2013, 3(7), 17-19,
http://www.discoveryjournals.com/medicalscience.htm

© 2013 Discovery Publication. All Rights Reserved

SUMMARY OF RESEARCH

This sero-prevalence study was helpful; as it provided information about prevalence of hepatitis B virus infection in and around Kanchipuram. Effective childhood immunization programmes should be undertaken to reduce the disease burden.

DISCLOSURE STATEMENT

Financial support for this research work was provided by MAHER University, Chennai, India.

ACKNOWLEDGEMENT

Dean of Meenakshi medical college and MAHER University

REFERENCES

1. Adoga MP, Gyar SD, Pechulano S, Bashayi OD, Emiasegen SE, Zungwe T et al. Hepatitis B virus infections in apparently healthy urban Nigerians: data from pre-vaccination tests. *J Infect Dev Ctries.,* 2010, 4(6), 397-400
2. Amarapurkar DN. Telbivudine. A new treatment for chronic hepatitis B. *World J Gastroenterol*., 2007, 13(46), 6150-6155
3. Chisari FV et al. Hepatitis B Virus Immunopathology. *Springer Semin Immunopathol.,* 1995, 17(2-3), 261-81
4. Chowdhury A. Epidemiology of hepatitis B virus infection in India. *Hep B Annual.,* 2004, 1,17-24
5. Chowdhury A, Santra A, Pal S, Chakravarty R, et al. Community based epidemiological study of Hepatitis B virus infection (HBV). *Indian Journal Gastroenterol.,* 2001, 20(Suppl 2) A2
6. Davaalkham D, Ojima T, Nymadawa P, Tsend N, Lkhagvasuren T, Wiersma S et al. Seroepidemiology of hepatitis B virus infection among children in Mongolia: results of a nationwide survey. *Pediatr Int.,* 2007, 49(3), 368-74
7. Data on file (Hepatitis B Virus), *Tulip Diagnostics* (P) Ltd
8. Gitlin Norman. Hepatitis B: diagnosis, Prevention and Treatment. *Clinical Chemistry.,* 1997, 43:8(B), 1500-1506
9. Interpretation of Hepatitis B Serologic Test Results. In http://www.cdc.gov/hepatitis/hbv.
10. Japhet MO, Adesina OA, Donbraye E, Adewumi MO. Hepatitis B Core IgM antibody (anti-HBcIgM) among hepatitis B Surface antigen (HBsAg) negative blood donors in Nigeria. *Virology Journal,* 2011, 8, 513-514
11. Lee WM. Hepatitis B virus infection. *N Engl J Med.,* 1997, 337, 1733-45
12. Lok AS. Chronic hepatitis B. *N Engl J Med.,* 2002, 346, 1682-1683
13. Lok AS, Heathcote EJ, Hoofnagle JH. Management of hepatitis B: 2000 - Summary of a workshop. *Gastroenterology* 2001, 120, 1828-53
14. Schmidt M, Nubling CM, Scheiblanres H, Chudy M, Walch LA, Seifried E, Roth WK, Hourfar MK. Anti-HBC screening of blood donors: a comparison of nine anti-HBc test. *Vox sang* 2006, 91, 237-243
15. Singh K, Bhat S, Shastry S. Trend in seroprevalence of Hepatitis B virus infection among blood donors of coastal Karnataka, India. *J Infect Dev Ctries,* 2009, 3(5), 376-379
16. Tandon BN, Acharya SK, Tandon A. Epidemiology of hepatitis B virus infection in India. *Gut.,* 1996, 38 (suppl 2), S56-S59
17. Wang YB, Chen EQ, Cui YL, Zeng L, Wang YJ, Tang H. Seroprevalence of hepatitis B virus markers in individuals for physical examination in West China Hospital, China. *Eur Rev Med Pharmacol Sci.,* 2011, 15(6), 592-6
18. Zhang H, Li Q, Sun J, Wang C, Gu Q, Feng X et al. Seroprevalence and risk factors for hepatitis B infection in an adult population in Northeast China. *Int J Med Sci.*, 2011, 8(4), 321-31

© 2013 Discovery Publication. All Rights Reserved