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A cross-sectional study on the prevalence of Hepatitis B virus infection among patients attending a tertiary care hospital in rural area of Kancheepuram District, Tamil Nadu

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Abstract

Background

Hepatitis B virus (HBV) infection is one of the major global health problems. As per World Health Organization (WHO) 600,000 people die every year due to HBV infection (ref1) The prevalence of HBV infection in India varies from 1-13% with an average of 4-7%.The average estimated carrier status of HBV in India is 4% with a total pool approximately 36 million carriers. Wide variation in socio-economic status and health factors in different regions explain variation in carrier rates from one part of the country to another.

Aim

The present study has been done to know the prevalence of Hepatitis B virus infection in rural population of Thiruporur area Tamil Nadu and to evaluate an ideal screening method for the detection of Hepatitis B virus infection in the study population.

Materials & Methods

A total of 100 blood samples were collected aseptically from patients attending the tertiary care hospital in rural Kancheepuram district of Tamil Nadu after obtaining their consent. Their serum samples were screened for Hepatitis B virus surface antigen (HBsAg) using conventional commercial ELISA and rapid Immunochromatographic Kits as per manufacturer's instructions.

Results

The results of HBsAg screening by rapid Immunochromatography showed nine out of 100 samples (9%) to be positive, while screening for HBsAg by ELISA revealed 15 out of 100 (15%) to be positive. Different variables like age, sex, nature of partipants and their educational qualifications were analysed.it was observed that out of 36 males and 64 females, seven males and eight females were positive for HBsAg by ELISA while five males and four females were positive by rapid Immunochromatography. Regarding the distribution of HBsAg positivity among participants, Symptomatic individuals showed a higher HBsAg positivity than the asymptomatic subjects. It was also observed that higher proportions of illiterates were positive for HBsAg when compared to educated individuals.

Conclusion

HBsAg screening of participants by two different methods namely rapid Immunochromatography and ELISA revealed 100% sensitivity by ELISA compared to that of 60% sensitivity by rapid Immunochromatographic method.

Key words: Hepatitis B virus, Hepatitis B virus surface antigen, Enzyme Linked Immuno Sorbant Assay, Rapid Immunochromatography.

1. Introduction

Hepatitis B Virus (HBV) infection is a major global health problem. As per World Health Organisation (WHO), an estimated 600,000 people die every year. The HBV infection is 10% in developing Nation like Asia and 0.5% in developed nation like United States and Northern Europe. [1] About 2 billion people are infected with HBV worldwide and 400 million among them are suffering from chronic HBV infection. Prevalence of HBV in India varies from 1-13%, with an average of 4.7 % [2]. The average estimated carrier rate of HBV I India is 4%, with a total pool of approximately 36 million carriers [3]. As per Region wise prevalence in India it was estimated that the lowest prevalence rate has been observed in

Chandigarh in northern India and highest prevalence rate has been observed in Chennai in South India. [3] HBV infection has the highest prevalence among young adults and adults as compared to children [4, 5]. Prevention of HBV infection is mainly by Hepatitis B vaccination which is mandatory and being included in the vaccination schedule which has been started only 10 years ago. Wide variations in social, economic and health factors in different regions explain variations in carrier rates from one part of country to another. The reason for HBV infection is lack of proper health care facilities, low economic status, poor hygiene, lack of public awareness about the major communicable disease such as HBV, HIV and HCV. Apart horizontal(bites, lesions, sanitary habits, sexual contact ,intravenous drug use), and vertical modes of transmission, certain traditional practices like tattooing, ritual body piercing often serve as potential sources of spread of HBV infection in a community. Infection with HBV leads to wide spectrum of clinical presentation ranging from asymptomatic carrier status to acute self- limiting infection or fulminant hepatic failure, chronic hepatitis with progress to cirrhosis and hepatocellular carcinoma(HCC) [2, 6]. Blood donors constitute the major risk group among adults for HBV infection in India, with a HBsAg positivity rate of 14%. Since there are many asymptomatic carriers who may be a potential source for the disease transmission, a generalized screening among rural population would be of immense help to reveal the prevalence rate of HBV in a given community. Hence we have taken up the present study to screen for HBV prevalence and to evaluate an ideal screening method for the detection of HBV among rural population who are attending the tertiary care hospital in Kancheepuram district, Tamil Nadu, India.

2. Materials and Methods

The present study was carried out after obtaining approval from the Institutional Ethical Committee. All the participants who were willing to take part in the study were individually explained about the importance of the study and their vaccination status were obtained. Individuals who had HBV vaccination were excluded from the study. The details of individual patients who were willing to be screened for HBV infection were obtained by providing them a questionnaire and information on age, sex, occupation, education, marital status, past history of jaundice, surgery, blood transfusion, and tattooing were obtained. A total of 100 blood samples were collected aseptically from patients attending a tertiary care hospital of rural area of Kancheepuram district of Tamil Nadu after obtaining the consent from them. The blood samples thus collected were centrifuged at 3000 rpm for 10 minutes to separate the serum samples and the sera were stored in screw capped vials at – 20 °c until used. All the serum samples were subjected for HBsAg screening using two different commercial diagnostic kits namely the rapid Immunochromatographic test kit and by Enzyme Linked Immunosorbent Assay (ELISA) kit. The serum samples which were initially screened for HBsAg using the rapid immuno chromatographic method were also subsequently screened for HBsAg positivity by ELISA method as per manufacture's instruction and the ELISA plate was read at 450 nm wavelength. The results of the immunochromatographic method for the detection of HBsAg were compared with that of HBsAg detection by ELISA for their sensitivity and specificity.

3. Results

The prevalence of HBV infection among 100 participants who attended the tertiary care hospital were analysed by screening their serum samples for HBsAg by two commercially available diagnostic kits namely, the rapid Immunochromatographic method and ELISA. The results of HBsAg screening by rapid Immunochromatographic method showed, 9 out of 100 samples (9%) to be positive (Table-1), while screening by ELISA revealed 15 out of 100 samples (15%) to be positive for HBsAg (Table-2). Different variables like age, sex, nature of participants and educational qualifications of the participants were analysed. It was observed that out of 36 males and 64 females, 7 males and 8 females were HBsAg positive by ELISA while 5 males and 4 females were positive by rapid method (Table-1&Table-2). Participants between age groups 20 to 40 years showed a higher number of HBsAg positivity both by rapid as wells as by ELISA methods (Table-1 &Table-2). Distribution of participants who were screened for HBsAg include symptomatic individuals (40), asymptomatic individuals (33) and volunteers (27) (Fig-1) The HBsAg positivity was higher in symptomatic individuals followed by volunteers and asymptomatic participants both by rapid and by ELISA methods (Table-1 &Table-2). Regarding the educational status it was observed that a higher proportion of illiterates were positive for HBsAg when compared to educated individuals (Table1&Table2). HBsAg Screening of participants by two different diagnostics methods namely the rapid immunochromatography and ELISA revealed 100% sensitivity by ELISA when compared to that of rapid immunochromatography method (sensitivity 60%).(Table-3).

Table 1: Test results for Immunochromatography (n=100)

Variables		No.Of Patients Tested	Positive Results
Sex	Male	36	5
	Female	64	4
Age	<20	8	-
	20-40	45	6
	40-60	42	3
	>60	5	-
Nature Of	Symptomatic	40	4
Participants	Asymptomatic	33	2
	Volunteers	27	3
Education	Literate	24	1
	Illiterate	76	8

No. Of Patients Tested For Hepatitis B Virus - 100
No. Of Patients Postive For Hepatitis B Virus - 9

Table 2: Test results for ELISA (n=100)

VARIABLES		NO.OF PATIENTS TESTED	POSITIVE RESULTS
SEX	MALE	36	7
	FEMALE	64	8
AGE	<20	8	1
	20-40	45	11
	40-60	42	3
	>60	5	-
Nature of participants	Symptomatic	40	6
	Asymptomatic	33	4
	Volunteers	27	5
Education	Literate	24	3
	Illiterate	76	12

No. Of Patients Tested For Hepatitis B Virus – 100
No. Of Patients Postive For Hepatitis B Virus- 9

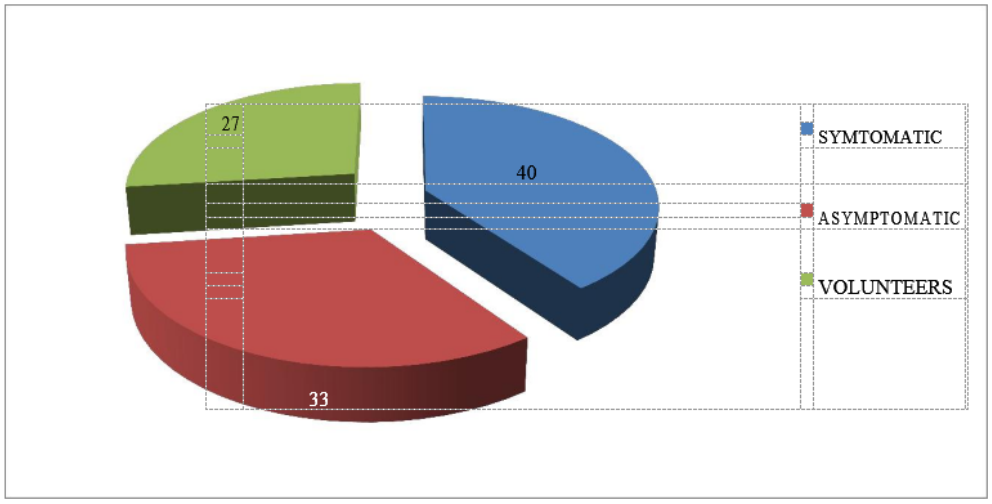
Table-3: COMPARISON OF RAPID TEST VS ELISA IN SERODIAGNOSIS OF HBV (HBsAg)

	ENZYME IMMUNO ASSAY (ERBALISA)		
	POSITIVE	**NEGATIVE**	**TOTAL**
RAPID TEST			
POSITIVE	**9**	**0**	**9**
NEGATIVE	**6**	**85**	**91**
	15	**85**	**100**

$$\text{Sensitivity} = \frac{a}{a+c} \times 100 = \frac{9}{15} \times 100 = 60\%$$

$$\text{Specificity} = \frac{d}{b+d} \times 100 = \frac{85}{85} \times 100 = 100\%$$

Fig 1: Distribution of participants for HBV screening (n=100)



4. **Discussion**

There are wide variations in social, economic and health factors in different regions of India, which may explain the differences in the HBV carrier rates reported by different investigators which are very different from HBsAg positivity [8, 9, 10, 11]. After the discovery of the Australia

antigen [12], hepatitis B surface antigen (HBsAg) has been the principal target for laboratory testing to identify active infection by HBV. Though earlier studies have reported the highest prevalence of HBsAg positivity (15.9 %) and the lowest prevalence of HBsAg positivity (0.97%) [7, 13], the present study showed a sero prevalence of 15 % of HBsAg positivity among patients who attended the tertiary care hospital. The higher rate of prevalence may be attributed to the fact that, all those patients who participated in our study were referred for different ailments from various medical and surgical departments. Further, more community based studies are needed to find out the real prevalence rate among the population. Comparative evaluation of two commercially available diagnostic kits for screening HBsAg revealed ELISA to be more sensitive (100%) in detecting the seropositivities, while the rapid Immunochromatographic method could detect strongly positive cases and missed weakly positive cases showing a sensitivity of 60%.Our study revealed a higher participation of females (64%) while compared to males (36%) and there was no significant difference in their HBsAg positivity status. Age group between 20 to 40 years showed a higher HBsAg Positivity (73.3%) compared to other age groups suggesting the possibility of an early exposure to HBV infection. Since there were no paediatric subjects included in our study, we could not avail the data of HBV exposure in children to rule out the vertical transmission among them. Among the distribution of participants who took part in the study only minor differences were noted in their HBsAg positive status. Regarding the educational status of the participants, we have observed that, illiterates had higher HBsAg positivity (80%) compared to literates coinciding the observations of Tandon *et al.*[2] Our study did not include participants with high risk behaviours like commercial sex workers, healthy volunteer blood donors and intravenous drug addicts.

5. Conclusion

The present study has revealed some original observations on the prevalence of HBV infection among rural people who were hardly subjected for HBsAg screening in the past. However, more detailed studies involving large numbers of sample size would reveal the exact carrier rate and also throw some light on the familial clustering of HBV infection among this community. The comparative evaluation of screening for HBsAg using two commercial diagnostic kits proves the superiority of ELISA over the rapid Immunochromatographic method. There are several rapid Immunochromatographic methods claiming their sensitivities and most of the primary health centres routinely use these kits due to their easy performance and cost effectiveness. This study brings out the need for the development of efficient rapid immunodiagnostic kits and confirms the HBsAg positive samples with the conventional ELISA method in order to prevent false negativity.

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