PREVALENCE OF HEPATITIS B AND HEPATITIS C INFECTIONS IN PATIENTS AND HEALTHY BLOOD DONORS

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ABSTRACT

Aim: *To study the prevalence of HBsAg and HCV antibodies in patient population versus healthy blood donors (voluntary and replacement).*

Material & Methods: *For both the parameter, rapid immunochromatographic kits were used followed by specific ELISA tests for patient population and ELISA screening in blood bank.*

Results*: The HBsAg seropositivity was comparable in both groups and lower than the national prevalence. HCV antibodies seropositivity was significantly higher in patient population as compared to blood donors.*

Conclusion*: Inclusion of immunization against hepatitis B virus in the national program will help to curb its spread but for control of HCV, measures like micro screening of blood donors and checking drug addiction needs to be undertaken.*

Keywords: *Hepatitis B surface antigen (HBsAg), Hepatitis C virus (HCV), Seropositivity, Prevalence*

INTRODUCTION

Blood borne hepatitis viruses include Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Hepatitis D Virus (HDV). These hepatotropic viruses possibly lack efficient means of host to host transmission. To compensate for this limitation, these viruses tend to persist for years, almost up to lifetime, in their hosts and circulate in peripheral blood. Thus, on apparent or in apparent percutaneous exposure to blood or blood products, these get transmitted.[1]

Although there has been extensive vaccination against HBV in many countries, acute or chronic viral hepatitis due to HBV and HCV, still ranks among the most frequent reportable infectious diseases throughout the world even after considerable underreporting. These affect several hundred million people worldwide, thus representing major health and diagnostic issues.[1]

HBV is a cause of about 15-30% of acute hepatitis in India.[2, 3] On the other hand, HCV causes most cases of post transfusion hepatitis.[4, 5] Acute infection by HCV is usually benign and asymptomatic. Clinically, it has remarkable ability to persist and produce chronic and irreversible liver damage with long term consequences being more severe than HBV. Due to this reason and because of non-availability of vaccine, Hepatitis C is presently the major public health concern associated with hepatitis viruses.[1]

Although both HBV and HCV have diverse genomes and replication strategies, but their pathologic effects on liver are similar and lack any reliable clinical clues about the specific infecting viruses. Both HBV and HCV have an insidious onset and irregular course of disease, so the clinicians have to depend extensively on the diagnostic laboratory for confirming the clinical disease, identifying the causative virus and to evaluate disease progression and outcome. As these viruses are not easily cultivable in vitro, depending on their isolation for diagnosis is impractical. The diagnosis in laboratory, therefore, relies on immunoassays demonstrating the viral antigen or their corresponding antibodies.

Immunologically, the key marker for diagnosis of HBV infection is Hepatitis B surface antigen (HBsAg). This can be demonstrated in blood 2-6 weeks prior to biochemical evidence of liver damage and remains positive throughout the course of infection, both acute and chronic. Commercial enzyme immunoassays (EIA) of various formats are currently used by most laboratories and show excellent specificity and sensitivity.[1]

The diagnosis of HCV is based principally on detection of antibodies to recombinant HCV polypeptides. There have been several "generations" of enzyme immunoassays (EIAs), that measure antibodies directed against NS4, core, NS3 and NS5 sequences.[6-8] The sensitivity of third generation assay is estimated to be 97%, and it can detect HCV antibodies within 6 to 8 weeks of exposure.[9,10] These assays measure the HCV infection, not immunity.

This study aims to assess the prevalence of HBsAg and HCV antibodies in the population attending this hospital from the surrounding areas and to compare this prevalence with the healthy blood donors to get a clear perspective about the status of these two infections smoldering in the population at large.

MATERIAL AND METHODS

The study was conducted in the Microbiology Department, Gian Sagar Medical College and Hospital, Punjab. The period of study was from January 2012 up to December 2014. The patient profile included all inpatient as well outpatient samples received for HBsAg and HCV screening in the department. Data pertaining to HBsAg and HCV was also collected from blood bank of the hospital. The blood bank profile included both voluntary and replacement blood donors.

In the microbiology department, all the specimens were screened using rapid immunochromatographic assays for both HBsAg and HCV antibodies using Hepacard (J.Mitra & Co.) and TRI-DOT (J.Mitra & Co.) respectively. Hepacard is based on the antigen capture, or "sandwich" principle. It uses monoclonal antibodies conjugated to colloidal gold and polyclonal antibodies immobilized on a nitrocellulose strip in a thin line. The HCV TRI-DOT is a fourth generation assay for detecting antibodies against HCV. It utilizes a unique combination of modified HCV antigens from the putative core, NS3, NS4 & NS5 regions of the virus to selectively identify all subtypes of Hepatitis C virus in human serum/plasma with a high degree of sensitivity and specificity.

All the specimens turning positive on screening test or giving doubtful results were confirmed by respective ELISA (ErbaLisa) tests. The ErbaLisa Hepatitis B is based upon the use of a solid phase prepared with polyclonal anti-HBsAg. Detection is carried out using monoclonal anti-HBsAg. This system of using a poly-mono blend of antibodies aims at achieving high assay sensitivity and specificity respectively. The ERBA ELISA HEPATITIS C is a third generation solid phase immunoassay, utilizing a mixture of synthetic peptides and recombinant proteins of HCV i.e., CORE, NS3, NS4 and NS5 for detection of HCV antibodies present in human serum and plasma.

As regards blood bank, all donor specimens were screened by respective ELISA (Biorad/ErbaLisa) tests for HBsAg and HCV antibodies. All the tests were performed in accordance with the manufacturer's instructions with adequate controls.

The statistical analysis of data was done using Pearson Chi-square test for comparison in frequencies.

RESULTS

In the Microbiology department, a total of 17784 patients were screened for Hepatitis B antigen and 18233 were screened for Hepatitis C antibodies over a period of three years from January 2012 to December 2014. In the Blood bank, a total of 12329 donors (both voluntary and replacement) were screened for both HBsAg and HCV antibodies over the same three years period. The year wise breakup is shown in the table 1.

Table 1: Number of patients and donors screened over 3 year period

Year	Microbiology Department		Blood bank	
	HBsAg	HCV	HBsAg	HCV
2012	6020	6234	4696	4696
2013	5882	5982	3337	3337
2014	5882	6017	4296	4296
Total	**17784**	**18233**	**12329**	**12329**

As seen in table1, the year 2013 showed a mild decline in the number of patients and donors for no specific reasons.

The incidence of positivity for both hepatitis B surface antigen and hepatitis C antibodies in the patient population and healthy blood donors is shown in table 2.

Table 2: Incidence of Hepatitis B &Hepatitis C

	Patients				Blood donors				Total	
Year	HBsAg		HCV		HBsAg		HCV		HBsAg	HCV
2012	74/6020	1.23%	198/6234	3.17%	76/4696	1.62%	67/4696	1.43%	150/10716 (1.4%)	265/10930 (2.4%)
2013	95/5882	1.61%	181/5982	3.03%	26/3337	0.78%	50/3337	1.49%	121/9219 (1.3%)	231/9319 (2.48%)
2014	76/5882	1.29%	262/6017	4.35%	55/4296	1.28%	58/4296	1.35%	131/10178 (1.28%)	320/10313 (3.1%)
Total	**245/17784**	**1.38%**	**641/18233**	**3.5%**	**157/12329**	**1.27%**	**175/12329**	**1.42%**	**402/30113 (1.33%)**	**816/30562 (2.67%)**

The incidence of Hepatitis B in the patient population shows no significant difference ($p>0.05$) over the three year period. But a significant increase in the incidence of HCV antibodies test positivity from 3.17% to 4.35% ($p<0.001$) can be seen from the year 2012 to 2014.

In case of blood bank, there is not much difference in the prevalence of HBsAg and HCV antibodies positivity in blood donors over three year period. A significant decrease ($p<0.001$) in the %positivity of HBsAg is seen in the year 2013 whereas, HCV antibodies positivity remained consistent over the three year period.

On comparison between the prevalence of seropositivity of HBsAg in the patient population versus blood donors, it was seen that there was no significant difference ($p>0.05$) in the HBsAg positivity rate as seen in table 2. In the patient population, the HBsAg seropositivity rate is seen to be consistent over the three year period, as is also the case in blood donors except in 2013 when the rate was seen to be significantly lower.

In contrast, there was a significant difference ($p<0.001$) in the seropositivity of antibodies against HCV in patient population and blood donors as seen in table 2. The HCV antibodies seropositivity is significantly high in the patient population than in blood donors. In fact, the percentage is significantly increasing in patient population over the years but in the blood donors it is mildly on the decrease.

Overall, the prevalence of hepatitis B among the population (both patients and healthy donors) over the three year period came out to be 1.33% and that of HCV in the same population as 2.67%.

DISCUSSION

In India hepatitis B is of intermediate endemicity (high endemicity >8%, intermediate endemicity 2-8%, low endemicity <2%)[11] with nearly 4% of the population being chronic hepatitis B virus carriers i.e. about 40 million people.[11] Moreover with 70% of the Indian population living in rural areas, one large study that systematically sampled a rural population reported the HBsAg prevalence rate of 2.97%.[12] Also in high risk population with repeated parenteral exposure, high rates of HBsAg positivity have been reported. In patients with thalassaemia and hemophilia, the positivity was 6-60%[13] and in blood donors 15-20%.[14, 15] A study from Chandigarh[16] in blood donors reported 0.65%-1.07% and from Pune 0.99%.[17]

In our study, the prevalence of HBsAg seropositivity (in both healthy and patient population) is found to be lower (1.33%) than the national data (2-4%).[11] The incidence of seropositivity of HBsAg in the patient and healthy blood donors is also comparable. This finding remains unexplainable as the frequency should have been lower in the blood donor group. The universal reason that there is immunization available against hepatitis B virus does not seem to be valid here as, if considered logically the minimum age of blood donation being 18 years, the youngest blood donor even on date would be born in 1997. In that period, awareness regarding immunization against hepatitis B was very low, so it is difficult to interpret the comparable results on this basis.

The prevalence of hepatitis C virus infection in India, as evaluated by anti HCV antibody positivity has been reported to be 1-2% among blood donors[18] which is comparable to our study, and 0.87% in the community.[19] The prevalence of HCV seropositivity in the community presenting as patients in our study is high as compared to the national statistics. This might be due to the fact that our patient population also includes high risk population like those on dialysis and thalassaemic patients. In such high risk groups, the anti HCV rates after 2002, when mandatory screening of blood donors for anti HCV was introduced in India, have been reported up to 4%[20] from previous 24%-28%. So the seropositivity for anti HCV is comparable in our study.

Other reasons for high anti HCV positivity in our study in patient population can also be attributed to firstly, maximum percentage being rural, all undergo preliminary treatment from quacks who use contaminated needles for injections and fluid transfusions, this being also more prevalent as patient satisfaction is more after being prescribed an injectable treatment in our locality. The second reason is due to the presence of menace of drug addiction (injectable) which is endemic in the state. Transmission of HCV has been found to increasingly occur through injecting drug use.[21] In a cross sectional study regarding burden of hepatitis C in people who inject drugs in India, the area in Punjab and Chandigarh was labeled as one of emerging epidemic (documented) with prevalence of HCV was in cities of Punjab viz. Amritsar being 48.7%, Ludhiana 25.6% and Chandigarh 51.1%[22]. Therefore, the high incidence of HCV antibodies in the population in our area.

In the world, an estimated 240 million people are chronically infected with hepatitis B (defined as HBsAg positive for at least 6 months). Prevalence is highest in sub-Saharan Africa and East Asia, where between 5-10% of adult population is chronically infected. In Middle East & Indian subcontinent an estimated 2-5% of general population is chronically infected.[23]

HCV has also been reported in virtually every country where it has been carefully evaluated. It is estimated that more than 170 million people are infected worldwide. [24] In developed nations, the HCV prevalence is typically 1%-2% in general population

and less than 0.5% among blood donors.[25] In comparison, 10-30% of general population is infected with HCV in Egypt. [26, 27] This has been attributed to a national campaign to treat schistosomiasis in Egypt with injection therapy and needles were frequently reused[28.]

CONCLUSION

To conclude, such studies on prevalence prove an eye opener for the existing scenario regarding diseases like hepatitis B and hepatitis C. However, conflicting the results of prevalence in an area or country for HBV carrier frequency, it is clear that immunization against HBV remains the most cost effective strategy in India[11, 29, 30] with its inclusion in the universal immunization schedule which has now started as "Mission Indradhanush", launched by the Central Government of India on 25th December, 2014. It aims to completely immunize children against seven diseases including hepatitis B, by the year 2020.

As no immunization is available against HCV, therefore, the screening of blood donors with sensitive techniques like NAT and chemilumescence and control of drug addiction menace in our region are the two important measures which can help to control the HCV prevalence.

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