

The Prevalence of Hepatitis B and C among the Passively Screened Population and Blood Donors in Haryana, India: A Retrospective Analysis

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Abstract:

Background. Hepatitis B and C are significant problems in India, especially in certain hotspots such as Haryana state. Since the data derived from the large-scale studies are unavailable, reports from individual centers or blood bank data are largely relied on to get a glimpse of the prevalence rate in India. This retrospective study aims to estimate the prevalence of hepatitis B and C based on the data collected from blood banks and passive screening of patients at PGIMS, Rohtak.

Methods. The first half of the dataset which contains routine hepatitis B and C test results was derived from blood banks. The other half of dataset was derived from the passive screening of patients from various outpatient departments and inpatient wards. The samples collected during the passive screening were tested for the positivity for HBsAg or anti-HCV antibody using ELISA tests.

Results. Analysis of the blood bank data revealed that the prevalence rates of HBsAg and anti-HCV antibody positivity were 0.80% and 0.81%, respectively, whereas the rates of the same derived from passive screening data were 5.23% and 5.18%, respectively.

Conclusion. The blood bank data did not depict the exact prevalence of hepatitis B and C. Concerns remain as they could possibly underestimate the rates. As opposed to that, the prevalence rates of passive screening data might possibly resemble to the genuine prevalence. Although it is sometimes inevitable to rely on blood bank data due to data paucity, cautiousness must be exercised when it comes to using this kind of data.

Keywords: Hepatitis B, Hepatitis C, HBsAg, Anti-HCV antibody, Blood banks, Passive screening

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1 Introduction

Globally, viral hepatitis is regarded as a principal public health issue as it has resulted in 1.34 million deaths in 2015, a number that is almost equivalent to tuberculosis-related deaths and higher than HIV-related deaths^[1]. Every year, approximately 1.4 million people die from liver cancer and cirrhosis related to viral hepatitis. Approximately 2 billion people have fallen victim to hepatitis B virus (HBV) infection, and about 185 million of this population were also infected with hepatitis C virus (HCV) and 20 million people with hepatitis E virus (HEV)^[2,3]. More than 90% children in high-endemic regions were reportedly infected by hepatitis A virus (HAV) before they have reached 10 years old even though few developed complications^[4]. Approximately 2.3 billion people are infected with more than one type of the hepatitis viruses worldwide, and an estimation of 325 million

people who live with chronic HBV or HCV infections has been reported^[5]. The population who are vulnerable to viral hepatitis include the people who have received multiple blood or blood product transfusions, people who use drugs, patients on hemodialysis, men having sex with men, female sex workers, sexual partners of infected people, migrants, prisoners, truckers, and close first-degree relatives and family members of the infected individuals.

Similarly, viral hepatitis is gradually becoming a public health problem of major concern in India. The positivity range for hepatitis B surface antigen (HBsAg) is from 1.1% to 12.2%, with an average prevalence of 3 – 4%, in the general population. Different geographical regions in India have markedly varying age-specific HBsAg seroprevalence. Certain parts or regions of the globe, such as Pacific Islands, South America's Amazon Basin, sub-Saharan region of Africa, East Asian countries, and the Balkan regions, have seen some of the highest recorded prevalence rates (>5%). About 240 million people are chronic HBsAg carriers^[6]. Unfortunately, the true prevalence of HBV in India is currently unknown due to a severe dearth of data. According to most studies, the prevalence of HBsAg positivity in India was reported to range between 2 and 8%^[7-9]. In India, the most commonly mentioned prevalence rate of HBV carrier is 4.7%, which is corresponding to a population of 56.5 million^[8]. The findings from many of these studies may not be able to truly reflect the prevalence at the national level because they are based on the data obtained from blood banks. According to a limited number of studies, about 40 million people in India are afflicted with chronic infection of hepatitis B^[3]. The large number of hepatitis B cases in India is caused by vertical transmission and unsafe needle practices, such as intravenous drug abuse and transfusions of blood or blood products.

Hepatitis B infection can be manifested as either acute or chronic condition and its severity can range from asymptomatic infection and mild disease to fulminant hepatitis^[9,10]. A feature of acute hepatitis B is the manifestation of acute inflammation whereas chronic hepatitis B infection is characterized by the sustained existence of blood or serum HBsAg for more than 6 months, which is a sign of persistent HBV infection^[10]. A few reports showed that both neonates (90%) and young children (20 – 60%) are at elevated risk for chronic hepatitis B as compared to adults (5%)^[11,12]. This finding is in line with the notion that most people who have chronic hepatitis B usually contracted the infection early in their lives, particularly soon after birth or in early childhood. Although chronic HBV infection is mostly inactive and does not cause any significant liver diseases, it may sometimes result in fibrosis and ultimately in cirrhosis, end-stage liver disease or hepatocellular carcinoma^[13]. Of note, chronic HBV infection is responsible for 40% of the hepatocellular carcinoma cases and 20 – 30% cirrhosis cases in India^[3]. Several longitudinal studies showed that the chronic hepatitis B patients that received no treatment were at an 8 – 20%

risk of developing cirrhosis in the subsequent 5 years^[11-15]. In addition, the range of annual incidence of hepatocellular carcinoma associated with hepatitis B is between <1% and 5%^[16]. This line of evidence insinuates the overwhelmed burden of HBV infection on other diseases.

The prevalence of chronic HCV infection in the adult population has been estimated at around 1.2 – 1.7% worldwide whereas the estimated figure in India is around 1%. In India, in absence of discrete studies, the estimated prevalence rate of hepatitis C is 1%^[17]. The prevalence of anti-HCV antibody positivity in the general population has been estimated to be between 0.09 and 15%^[4] and 6 – 12 million people were infected with hepatitis C in India^[5]. Chronic HCV infection accounts for 12 – 32% of hepatocellular carcinoma cases and 12 – 20% of cirrhosis cases^[4]. India has approximately 3 – 9 million individuals infected with active infections of HCV^[2]. The population at risk includes transfusion recipients of blood or blood product, especially from the donors before the implementation of large-scale testing of hepatitis C in India, that is, before 2001.

The HCV is a single-stranded RNA virus. Its lifecycle starts with the endocytosis of viral capsid by the hepatocyte which leads to the synthesis of new viral progenies that infect more new cells in the host on release^[18]. The symptoms of hepatitis C in the acute phase include generalized myalgia, nausea, vomiting, and upper abdominal discomfort due to mild hepatomegaly that causes the stretching of capsule. Around 5 – 20% of chronic hepatitis C patients may develop cirrhosis after 10 – 20 years and about a quarter of them may advance to hepatocellular carcinoma and end-stage liver disease. HCV is classified into seven genotypes. In India, HCV genotype 3 is more common in South India whereas genotype 4 is common in North India. The hepatitis C screening test involves the detection of anti-HCV antibodies and the confirmation test following positive screening result is a quantitative HCV RNA test^[17].

The main objective of this retrospective study is to estimate the prevalence of hepatitis B and C based on the data obtained from blood banks and passive screening setting. This is also to preliminarily evaluate the reliability of blood bank data for estimating the prevalence of hepatitis B and C.

2 Methods

This study was conducted at the Medical Gastroenterology Department and Microbiology Department of the Post Graduate Institute of Medical Sciences (PGIMS), Rohtak in collaboration with the Director General Health Services (DGHS), Haryana. Ethical approval was obtained from the concerned committee. The entire timespan for this study was from January 1 to December 31, 2019.

The first set of data was collected from the blood banks in Haryana state, India. This dataset comprises the number

of positive hepatitis B and C cases detected during blood donation. Proper consent was taken before blood taking. The data were included in this study without any selection criterion.

The second set of data was derived from passive screening of patient samples originated from various outpatient departments and inpatients wards at PGIMS, Rohtak. These patients sought for treatments in these outpatient departments or were admitted for treating different kinds of diseases. The age range of this mixed-gender patient group was from 10 to 82 years. The patient samples were screened for HBsAg and anti-HCV antibody positivity using enzyme-linked immunosorbent assay (ELISA). Five milliliters of blood were collected from each patient. Each blood specimen was divided into two aliquots: One was used for HBsAg detection and the other for anti-HCV antibody detection. The collected blood specimens were kept at room temperature for 2 h for clot formation and then centrifuged at 3000 rpm for 5 min to separate plasma. The plasma was then subjected to HBsAg detection using the MERILISA HBsAg ELISA kit (Meril Diagnostics, Gujarat, India) which has diagnostic sensitivity and specificity of more than 99.3% and 99.6%, respectively. The plasma was also used for anti-HCV antibody detection using MERILISA HCV ELISA kit (Meril Diagnostics, Gujarat, India) with a sensitivity and specificity of at least 99.5% in adherence to the manufacturer's instruction.

3 Results and discussion

Although the reports on the prevalence of HBV and/or HCV infections among blood donors^[19] and in patients with certain clinical conditions^[20,21] are available, the prevalence of these infections in the general Indian population is sparse. Thus, studies on the prevalence of HBV and HCV infections are warranted to understand their epidemiology and to formulate public health strategies for improving disease prevention and control^[21].

In the present study, out of the 175,342 blood donors, 1407 of them were found to be positive for HBsAg and 1427 were positive for anti-HCV antibody. Based on the blood bank data, the prevalence rates of HBsAg and anti-HCV antibody positivity were 0.80% and 0.81%, respectively (Table 1). In the case of passive screening data (Table 2), out of total of 51,440 patients who have been screened, 2690 of them were found to be positive for HBsAg, highlighting the prevalence of 5.23%. On the other hand, 2664 patients were found to be positive for anti-HCV antibody, determining its prevalence rate at 5.18%.

In our study, the overall prevalence rates of HBV were 0.81% and 5.23% based on the blood bank data and passive screening data, respectively. In 1995, the average estimated carrier rate of HBV in India was 4%^[22]. A community-based study revealed that the HBV prevalence

Table 1. Hepatitis B and C status of blood donors

	Number	Prevalence (%)
Total number of blood donors who were screened for hepatitis B and C	175,342	Not applicable
Number of blood donors positive for hepatitis B	1407	0.80
Number of blood donors positive for hepatitis C	1427	0.81

Table 2. Hepatitis B and C status of patients in passive screening

	Number	Prevalence (%)
Total number of patients who were screened for hepatitis B and C	51,440	Not applicable
Number of patients positive for hepatitis B	2690	5.23
Number of patients positive for hepatitis C	2664	5.18

in the urban and rural subjects in Tamil Nadu was 5.7% for HBsAg positivity^[23], which is comparable to our finding. In contrast, studies from West Bengal state^[24] and Kanpur city^[25] showed that 2.97% (227/7653) and 2.25% (450/20,000) of their respective populations were positive for HBsAg. The HBV prevalence rate varies among different populations, ranging from 0.1% in the developed countries to 20% in the developing nations^[26].

There is a considerable variation in the geographical distribution of HCV^[27]. In our study, the overall prevalence rates of HCV based on the blood bank data and passive screening data were 0.81% and 5.18%, respectively, but the latter is strikingly higher than the findings from Bangladesh^[23] and Tamil Nadu^[28]. The different districts of one state can too have different prevalence rates, depending on variables such as socio-economic factors, demographic profile, cultural habits, and availability of health facilities. In India, very few studies are available on the prevalence of HCV in general population. Community-based studies from the Indian states such as West Bengal^[29], Andhra Pradesh^[30], and Arunachal Pradesh^[31] reported that the HCV prevalence in these regions were 0.87%, 1.40%, and 7.89%, respectively. The first two had lower prevalence in comparison to our study whereas from Arunachal Pradesh had prevalence on higher side. The fact that these studies were carried out at different time-points in the past and their study durations were varying from each other highlights that (i) hepatitis C is a persistent public health problem in India for a long time and (ii) the prevalence rates in different geographical areas are variable.

The Government of India acknowledged the problem of hepatitis B and C and thus has launched National Viral Hepatitis Control Program (NVHCP) in 2018 under which free diagnostics, such as screening kits and viral

load tests, and treatment, are provided all over country to tackle this public health issue. Nevertheless, it would be more cost-effective if the transmission of these diseases can be prevented. Since both hepatitis B and C are blood-borne infectious diseases and have the common route of transmission, more stringent practices and strategies must be implemented and formulated to deter their widespread transmission. Some of the examples include safe injection practices, strict safety norms in blood banks, reduction of intravenous drug abuse, hygienic use of blade in barber shops or saloons, screening of pregnant mothers, administration of hepatitis B treatment at the 7th month of pregnancy, and neonatal vaccination.

In the current study, the lower prevalence rate being reported in blood banks can be attributed to the fact that most of the blood donors are healthy and asymptomatic, whereas the fact that the patients who sought medical consultation during the passive screening can account for the increased number of positive hepatitis B or C cases as a part of the screened patients might have chronic liver disease. This explains why the latter can lead to a more truthful reflection of prevalence of these infectious diseases. The main strength of our study is that it reconfirms the unreliability of using the blood bank data to estimate the prevalence rate of diseases. The optimistic interpretation of the blood-bank data-based prevalence rate, which is usually low as a majority of blood donors are healthy, may lead to ignorance of the insidious public health problem.

4 Conclusion

It is advisable not to rely on the blood-bank data for the estimation of the prevalence of hepatitis B and C as such a practice would undermine the problem. In contrast, the data collected from the passive screening of patients in outpatient departments and inpatient wards might yield prevalence rates that are closer to the rates estimated in community-based studies. Our study highlights the need of more regular screening for hepatitis B and C in the general Indian population so as to offer a glimpse into the exact gravity of the current situation. It is important to note that only with the accurate prevalence data can the government and policymakers formulate and strategize the control measures and health-care planning for the future.

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Conflict of Interest

The authors have no conflict of interest to declare.

Author contributions

P.M. conceived and designed this retrospective study. V.M. performed the data analysis. U.G. reviewed draft of paper. Y.S. gathered the data for analysis. P.S.G. and Pushkar conducted hepatitis B and C screening tests.

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