### **Original Research Article**

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# Seroprevalence of anti HCV antibodies among blood donors: a retrospective study from Haryana, India

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#### ABSTRACT

**Background:** HCV is known for its chronicity and leads to cirrhosis in about 10 to 20 per cent of patients and may further progress to hepatocellular carcinoma (HCC). The global seroprevalence of HCV among blood donors varies from 0.4 to 19.2 per cent and the estimated risk for HCV transmission is between 0.10 to 2.33 per million units transfused. ELISA is the most commonly used initial assay for detecting HCV antibodies. The purpose of the present analysis was to monitor the seroprevalence of anti-HCV antibodies in the blood donor population in a hospital based blood bank in north India for a period of 10 years (2007-2016), and to evaluate the trends over the years.

**Methods:** The purpose of the present analysis was to monitor the seroprevalence of anti-HCV antibodies in the blood donor population in a hospital based blood bank in north India for a period of 10 years (2007-2016), and to evaluate the trends over the years.

**Results:** Of the total 340078, 298421 (87.75%) collections were voluntary and 41657 (12.25%) were replacement collections. A prevalence of 0.72% of hepatitis C virus infection was seen among the donors from the period 2007-2016. The trend of hepatitis C prevalence among donors has been fluctuating while ranging from 0.51% to 0.89%.

**Conclusions:** For a safe blood service in our country, where comprehensive laboratory tests are neither possible nor pragmatic, it is best to switch over to 100% voluntary donations, as it is now established that only voluntary non-remunerated regular donation is the safest. Thus, one of our key strategies to enhance blood safety is to focus on motivating non-remunerated blood donors and phasing out even replacement donors. Since, no vaccine is presently available for immunization against HCV infection, transfusion transmitted HCV infection remains a potential threat to the safety of the blood supply.

Keywords: Donor, Hepatitis C, Infection, Replacement, Voluntary

#### **INTRODUCTION**

Transfusion of blood and blood products is a life-saving treatment modality. However, blood transfusion may lead to certain infectious and non-infectious complications in the recipients. The common transfusion transmissible infections (TTIs) include human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), malaria and syphilis; although many other infectious

agents like human T-cell lymphotropic viruses (HTLVs), West Nile virus (WNV), cytomegalovirus (CMV), parvovirus B19 and prions are known to be transfusion transmissible.<sup>1</sup> Furthermore, voluntary donors have been reported to be the safest group of donors because they usually have better health seeking behavior than the replacement blood donors and their intention is to donate blood to an unknown patient out of compassion.<sup>2</sup> Hepatitis C virus (HCV) was discovered in 1989 and belongs to the Flaviviridae family.<sup>3</sup> It has been shown to be the cause of up to 90 per cent of cases, previously known as Non A Non B (NANB) transfusion-related hepatitis.<sup>4</sup> The transmission of HCV occurs primarily through exposure to infected blood which may be due to blood transfusion, organ transplantation, intravenous drug use, body piercings, tattooing, haemodialysis and occupational exposure. Other modes of transmission include perinatal spread and high risk sexual behaviour. HCV is known for its chronicity and leads to cirrhosis in about 10 to 20 per cent of patients and may further progress to hepatocellular carcinoma (HCC).<sup>5,6</sup> The global seroprevalence of HCV among blood donors varies from 0.4 to 19.2 per cent and the estimated risk for HCV transmission is between 0.10 to 2.33 per million units transfused.7

In India, the Drug and Cosmetics (1st amendment) Rules 1992 (3) Act, mandates the testing of each unit of donated blood for the presence of markers of HIV, HBV, malaria and syphilis.<sup>8</sup> Subsequently, testing for markers of HCV was made mandatory in June, 20016. Tests used for the detection of HCV infection include the HCV antibody enzyme linked immunosorbent assay (ELISA), recombinant immunoblot assay (RIBA), and HCV RNA polymerase chain reaction (PCR). ELISA is the most commonly used initial assay for detecting HCV antibodies.<sup>9</sup>

The purpose of the present analysis was to monitor the seroprevalence of anti-HCV antibodies in the blood donor population in a blood bank in public sector of Haryana for a period of 10 years (2001-2010), and to evaluate the trends.

#### **METHODS**

It was a retrospectively record based study done at Blood Bank, Department of Transfusion Medicine, PGIMS, Rohtak, Haryana. All blood donations collected during the period of 10 years i.e. 2001-2010 were included. The donors were either voluntary or replacement donors. Replacement donors were either relatives or friends of patients. Before donation "Blood Donation Form" had been filled by every donor and this form had particulars about age, gender, address, and occupation, date of previous donation, any illness and medical treatment taken. The study was cleared by institutional ethics committee. The consent was taken. Donation taken only after physical examination carried out by the doctor.

As a routine practice, apparently healthy blood donors are selected by the trained medical staff at the department. Consent for infectious marker testing is obtained from all donors at the time of pre-donation counselling. All serum samples obtained at the time of whole blood donation are examined for various markers of infection including those of HCV. The donor serum samples are analyzed to detect anti-HCV antibodies by ELISA. All the samples that are found positive by ELISA on initial testing, are repeat tested in duplicate with the same sample. Samples that are found to be repeat reactive are considered positive.

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#### RESULTS

A period prevalence of 0.92% of Hepatitis C virus infection was seen among the donors from the period 2001-2010. Yearly distribution of HCV infection is given along in Table 1. Year wise percentage of HCV infection is also given along with. The trend of hepatitis C prevalence among donors has been ranging from 0.36% to 1.87%. Figure 1 shows the line diagram for the Hepatitis C infection prevalence.

## Table 1: Trends in hepatitis C seroreactive donorsover the study period.

Year	HCV seroreactive donors	HCV seroreactive donors (%)	Malaria cases
2001	84	0.36%	0
2002	113	0.46%	0
2003	399	1.59%	0
2004	474	1.87%	0
2005	224	0.83%	0
2006	251	0.96%	0
2007	179	0.75%	0
2008	200	0.8%	54
2009	240	0.66%	3
2010	284	0.61%	4
Total	2448	0.92%	61





Malaria parasite was found positive in a total of 61 donors which may be cases of relapse or prevailing hypnozoites. In 2008, maximum cases of malaria parasite were found which shows an outbreak nearby the study area.

#### DISCUSSION

In the present retrospective study, we evaluated the seroprevalence of hepatitis C virus among the blood donors in this region of Haryana. This study gave an overview of the epidemiology of the disease in the community. The data will help in evaluating the seroprevalence of the hepatitis C infection in India. The hepatitis C infection is spreading fast in India. Over one lakh people get infection by the deadly virus every year. According to the Indian National Association for the study of liver, nearly 12.5 million Indians are suffering from the hepatitis C diseases, with the death rate exceeding over one lakh. Hepatitis C has increasingly been found to be a significant aetiological agent which causes liver disease in India. The clinical manifestations include acute hepatitis, chronic hepatitis, cirrhosis, and hepatocellular carcinoma. Since hepatitis C is a transfusion transmissible infection hence it is mandatory to test all the blood donors for its presence. To ensure the transfusion of safe blood to the recipient, not only a mandatory screening of such infection markers is necessary, but it is also important to study the prevalence and risk factors of the HCV infection among the donor population.

Voluntary donors are considered best for blood donation as they come from low risk population whereas present scenario is that family/replacement donors still provide more than 45% of the blood collected in India. Such donors are supposed to be associated with a significantly higher prevalence of transfusion-transmissible infections (TTIs) including HIV, hepatitis B, hepatitis C, syphilis and malaria.<sup>10</sup>

A relatively low anti-HCV seroprevalence of 0.92 per cent in blood donors has been reported from Delhi.<sup>11</sup> However, two studies done in blood donors of Delhi reported relatively higher anti-HCV seroprevalence rates of 1.57 and 2.5 per cent, respectively.<sup>12,13</sup>

Studies from northern parts of India have reported HCV seroprevalence ranging from 0.53 to 5.1 per cent in blood donors.<sup>12,14,15</sup> In a recent study done in Hisar, Haryana, the seroprevalence of anti-HCV antibodies was calculated to be 1 per cent.<sup>16</sup> A study done in Orissa reported anti-HCV seroprevalence to be 1.98 per cent.<sup>17</sup> A study from Kolkata reported the seroprevalence of HCV as 350 per 100,000 donations in 2005.<sup>18</sup> HCV seropositivity in the western part of India has been reported to be 0.28 per cent by Garg et al.<sup>19</sup> In general, majority of studies carried out in India indicated anti-HCV antibody seroprevalence ranging between 0.4 and 1.09 per cent.<sup>20</sup>

The seroprevalence of anti-HCV antibody as observed in our donor population was relatively low as compared to other studies. This variation may be attributed to the difference in the sensitivities of ELISA kits used, effectiveness of donor screening to exclude donors with a history of high risk behaviour, pre-donation counselling and self-deferral by donors.

The prevalence of hepatitis C infection among our blood donor population was found to be 0.92 per cent using serological tests. Increased awareness in blood donors, self-rejection related to it and increased voluntary blood donors in comparison of replacement donors may be the reasons for low sero prevalence in this part of region.

Limitation of study is that males form the majority of blood donors which implies that the sero prevalence does not depict true representation of community. Also, drug abusers and people who are suffering from hepatitis C infection or taking treatment for the same are excluded from the study. Their number may too inflate the sero prevalence.

#### CONCLUSION

A high quality selection procedure for selection of blood donors and effective mass media campaign for hepatitis C infection are required for curtailing the increasing sero prevalence of HCV. Since, no vaccine is presently available for immunization against HCV infection, transfusion transmitted HCV infection remains a potential threat to the safety of the blood supply. Our country cannot afford the high treatment cost of HCV infection which is present only in apex institutions in metro cities only. The need of the hour is proper donor selection and screening of the eligible donors with mass education programmes to curtail the menace of hepatitis C.

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