

## Seroprevalence of anti-HCV antibodies among blood donors of north India

R.N. Makroo, Rimpleet Singh Walia, Mohit Chowdhry, Aakanksha Bhatia, Vikas Hegde & N.L. Rosamma

*Department of Transfusion Medicine, Indraprastha Apollo Hospitals, New Delhi, India*

Received May 9, 2012

**Background & objectives:** Transfusion of blood and blood products although considered as a life saving treatment modality, but may lead to certain infectious and non-infectious complications in the recipients. The purpose of this analysis was to monitor the seroprevalence of anti-HCV antibody in the blood donor population in a hospital based blood bank in north India, to evaluate the trends over the years (2001-2011).

**Methods:** Relevant information of all the blood donors who donated whole blood at the department of Transfusion Medicine, Indraprastha Apollo Hospitals, New Delhi from the January 1, 2001 to December 31, 2011 was retrieved from the departmental records. The number of donors who were found reactive for anti-HCV antibodies was calculated.

**Results:** Of the 2,06,022 blood donors, 1,93,661 were males and 12,361 were females. The percentage of whole blood donors found seroreactive for anti-HCV antibodies was 0.39 per cent (n=795). The seroprevalence of anti-HCV in male blood donors was 0.38 per cent (n=750) and the respective seroprevalence in female blood donors was 0.36 per cent (n=45). No significant change in the trend of HCV seroprevalence was observed over the period under consideration. Maximum seroprevalence of anti-HCV was observed in the age group of 18 to 30 yr (0.41%) and the minimum in the age group of 51 to 60 yr (0.26%).

**Interpretation & conclusion:** HCV seroprevalence in our study was 0.39 per cent and a decreasing trend with age was observed. No significant change in the trend of anti-HCV seroprevalence was seen over a decade. 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.

**Key words** Anti-HCV - blood donors - north India - seroprevalence

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>.

Hepatitis C virus (HCV) was discovered in 1989 and belongs to the Flaviviridae family<sup>1</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>2</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>3,4</sup>. The global seroprevalence of HCV among blood donors varies from 0.4 to 19.2 per cent<sup>5</sup> and the estimated risk for HCV transmission is between 0.10 to 2.33 per million units transfused<sup>1</sup>.

In India, the Drug and Cosmetics (1<sup>st</sup> 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>6</sup>. Subsequently, testing for markers of HCV was made mandatory in June, 2001<sup>6</sup>. 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>7</sup>.

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 11 years (2001-2011), and to evaluate the trends over the years.

### Material & Methods

This retrospective study was conducted in the department of Transfusion Medicine, Indraprastha Apollo Hospitals, New Delhi, after approval from ethical committee during January 1, 2001 to December 31, 2011. The hospital has a blood bank and the majority of blood supply comes from replacement donors. Each donor was included only once in the study.

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.

Tests were performed on fully automated ARIO walk away system (Ortho Clinical Diagnostics, Johnson & Johnson) from 2001 till 2004, using third generation ELISA kits (Ortho Clinical Diagnostics, Johnson & Johnson). From 2005 till 2011, all tests were done on a fully automated platform, EVOLIS using third generation ELISA kits for HCV antibodies (HCV Ab ELISA, Murex Diagnostics Ltd., UK).

Relevant information of all the blood donors who donated whole blood during 2001-2011 was retrieved from the departmental records. Of these, the donors found reactive for anti-HCV were selected.

Chi square test was employed to analyse the yearly trend of HCV seroprevalence during the 11 year period and to analyse the age distribution of anti-HCV reactive blood donors.

### Results & Discussion

Of the 2,06,022 blood donors, 1,93,661 (94%) were males and 12,361 (6%) were females. The percentage of whole blood donors found seroreactive for anti-HCV was 0.39 per cent (n=795). The seroprevalence of anti-HCV antibodies in male blood donors was 0.38 per cent (n=750) while in female blood donors it was 0.36 per cent (n=45).

To study the trend of HCV seropositivity during the study period Chi square goodness of fit was employed. No statistically significant change was observed over the period under consideration (Table I). Maximum seroprevalence of anti-HCV antibodies was observed in the age group of 18 to 30 yr (0.41%) and the minimum in the age group of 51 to 60 yr (0.26%). A clear trend of decreasing HCV seroprevalence with advancing age was observed and this trend was statistically significant ( $P < 0.05$ ) (Table II).

A relatively low anti-HCV seroprevalence of 0.66 per cent in blood donors has been reported from Delhi<sup>8</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>9,10</sup>.

Studies from northern parts of India have reported HCV seroprevalence ranging from 0.53 to 5.1 per cent

**Table I.** Time trend in HCV seroreactive donors with confidence intervals

Year	Total number of donors tested	Number of HCV seroreactive donors	HCV seroreactive donors	95 % CI Lower limit	95% CI Upper limit
2001	17,792	73	0.41	0.0032	0.0057
2002	18,333	68	0.37	0.0029	0.0047
2003	17,976	52	0.29	0.0022	0.0038
2004	16,040	54	0.34	0.0026	0.0044
2005	15,994	50	0.31	0.0024	0.0041
2006	18,278	75	0.41	0.0033	0.0051
2007	19,664	75	0.38	0.0030	0.0048
2008	21,069	86	0.41	0.0033	0.0050
2009	20,605	86	0.41	0.0034	0.0052
2010	19,515	84	0.43	0.0035	0.0053
2011	20,756	92	0.44	0.0036	0.0054

in blood donors<sup>9,11,12</sup>. In a recent study done in Hisar, Haryana, the seroprevalence of anti-HCV antibodies was calculated to be 1 per cent<sup>13</sup>. A study done in Orissa reported anti-HCV seroprevalence to be 1.98 per cent<sup>14</sup>. A study from Kolkata reported the seroprevalence of HCV as 350 per 100,000 donations in 2005<sup>15</sup>. HCV seropositivity in the western part of India has been reported to be 0.28 per cent by Garg *et al*<sup>16</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>17-20</sup>.

The seroprevalence of anti-HCV antibody as observed in our donor population was relatively low as compared to other studies. This variations 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.

In Pakistan, it is estimated that seroprevalence of hepatitis C virus antibodies among healthy blood donors from different parts of the country, varies from 0.27 to 6.8 per cent<sup>21</sup>. The pooled prevalence of HCV infection among blood donors of China was alarmingly high before 1998 (12.87%). However, it dramatically

decreased to 1.71 per cent after 1998 when the government prohibited professional donors from donating blood<sup>22</sup>. In the United States sero prevalence in HCV of blood donors was estimated to be 0.3 per cent<sup>23</sup>. In Greece also a low prevalence (0.2 to 0.4%) of antibodies to HCV has been reported<sup>24</sup> and a similarly low rate (0.13%) was also reported from Iran<sup>25</sup>. Lower rates of anti-HCV antibodies have also been reported in blood donors of Turkey (0.07%)<sup>26</sup>, Saudi Arabia (0.4%)<sup>27</sup>, Mexico (0.84%)<sup>28</sup> and Kenya (0.9%)<sup>29</sup>.

The reported variation in the prevalence of anti-HCV antibodies among blood donors in different regions of the world may be attributed to the differences in the type, literacy rate and level of awareness among the blood donors. Moreover, the differences in the testing methodology employed and the extent of its regulation may also have been the factors contributing to the observed differences<sup>30</sup>.

The anti-HCV seropositivity showed a decreasing trend with age in our study. Maximum seroprevalence of anti-HCV antibodies was observed in the age group of 18 to 30 yr, as also shown in another study from Delhi<sup>9</sup>. On the contrary, some studies have reported an increasing trend of anti-HCV seroprevalence with advancing age<sup>24,30</sup>.

In conclusion, the percentage of whole blood donors found seroreactive for anti-HCV was 0.39 per cent. The anti-HCV seropositivity followed a decreasing trend with age, maximum being in the age group of 18 to 30 yr. 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.

**Table II.** Age distribution of HCV seroreactive donors

Age (yr)	Total number of donors	Number (%) of HCV seroreactive donors
18-30	89,826	368 (0.41)
31-40	68,193	274 (0.40)
41-50	36,466	123 (0.34)
51-60	11,537	30 (0.26)

### Acknowledgment

The authors acknowledge the efforts and competence of the entire technical staff of the Department of Transfusion Medicine, Indraprastha Apollo Hospital, New Delhi.

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Reprint requests: Dr R.N. Makroo, Director, Department of Transfusion Medicine, Gate No. 9, Indraprastha Apollo Hospitals Sarita Vihar, Mathura Road, New Delhi 110 044, India  
e-mail: makroo@apollohospital.com / raj\_makroo@hotmail.com