

Seroprevalence of Hepatitis C Virus in Voluntary Blood Donors at a Tertiary Care Hospital, Ahmedabad, India

Henisha Tulsidas Tahiliani, Asha Poonamchand Purohit, Vipul Bachubhai Prajapati, Puja Bhavesh Jarwani

Department of Pathology and Medicine, GCS Medical College, Hospital and Research Centre, Ahmedabad, Gujarat, India

Abstract

Background: Hepatitis C virus (HCV) is the most common cause of post transfusion non-A, non-B hepatitis worldwide. The prevalence of HCV in blood donors in high-income countries ranges from 0.002% to 0.05%, in middle-income countries ranges from 0.03% to 0.80%, and in low-income countries, prevalence varies from 0.50% to 2.23%. **Objectives:** The objectives of this study are to assess the seroprevalence and the trend of HCV in healthy voluntary blood donors at a tertiary care hospital in Ahmedabad over a period of 3 years. **Settings and Design:** Observational, retrospective study. **Materials and Methods:** During January 2017 to December 2019, 9477 voluntary blood donors were tested for the presence of anti-HCV antibody by using a 3rd-generation enzyme-linked immunosorbent assay test. **Statistical Analysis Used:** Data were statistically analyzed by using the Chi-square test, and Chi-Square test for linear trends using the Statistical Package for the Social Sciences (SPSS) software trial version 19. **Results:** Out of 9477 voluntary blood donors, 9229 (97.38%) donors were male and 248 (2.62%) were female. Ten donors (0.11%) were positive for anti-HCV. All seropositive donors were male. Out of total 0.11% seropositive donors, maximum (0.07%) were within the age group of 21–30 years. Seroprevalence of HCV showed a statistically significant decreasing trend over 3 years. **Conclusion:** Hepatitis C is a common cause of transfusion-related hepatitis. Early identification of persons with chronic HCV infection would enable infected persons to receive the necessary care and treatment to prevent or delay the onset of liver disease.

Keywords: Hepatitis C virus, seroprevalence, voluntary blood donors

INTRODUCTION

Donor blood helps the patient in many ways, but it also carries the risk of transmitting transfusion-transmitted infections (TTIs) in the absence of proper donor screening. The ultimate goal of a blood transfusion service is the provision of safe and adequate supply free from TTIs.^[1] The Government of India mandates screening of all blood donors for five major TTIs: Human immunodeficiency virus (HIV), Hepatitis B virus (HBV), hepatitis C virus (HCV), syphilis, and malaria as per the Drugs and Cosmetics Act. HCV is the most common cause of post transfusion Non-A, Non-B hepatitis all over the world.^[2] It is a major cause of liver disease worldwide, with approximately 170 million people affected.^[3] Regions estimated to have a high prevalence of HCV in the general population (>3.5%) are Central and East Asia, North Africa/Middle East; those with a moderate prevalence (1.5%–3.5%) include South and South-East Asia, sub-Saharan Africa, Latin America (Andean, central, and southern regions), the Caribbean, Oceania, Australia, and Central, Eastern, and

Western Europe, whereas low-prevalence (<1.5%) regions include Asia-Pacific, Latin America, and North America.^[4]

HCV is a member of the *Flaviviridae* family. It is a 60-nm sized, spherical, enveloped, single-stranded RNA virus. HCV possesses three structural and six nonstructural proteins. Structural proteins include nucleocapsid core protein C and two envelope glycoproteins E1 and E2. Non-structural proteins include NS1-NS5B. The E2 envelope protein is the hypervariable region that mutates rapidly and probably plays a key role in the virus ability to escape neutralization, giving rise to multiple genotypes, and subtypes.^[5]

Address for correspondence: Dr. Puja Bhavesh Jarwani, 40, Niharika Bungalows, Nr. Azad Society, Opp. Himmatlal Park, Ambawadi, Ahmedabad - 380 015, Gujarat, India. E-mail: pujajarwani@gmail.com

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The HCV is a blood-borne virus: The most common modes of infection are through exposure to the small quantities of blood. This may happen through injection drug use, unsafe injection practices, unsafe health care, transfusion of unscreened blood and blood products, and sexual practices that lead to exposure to blood.^[6] The average incubation period of HCV is 9 weeks; it varies from 4 to 26 weeks. 80%–90% of HCV infection is reported to progress to chronic infection, of which 20% may progress to cirrhosis and hepatocellular carcinoma.^[3] In about 85% of individuals, the clinical course of the acute infection is asymptomatic, and therefore, patients frequently present with advanced disease and may transmit infection to others.^[3,4] Globally, an estimated 71 million people have chronic HCV infection. The World Health Organization (WHO) estimated that in 2016, approximately 399,000 people died from hepatitis C, mostly from cirrhosis and hepatocellular carcinoma.^[6] Seroconversion in HCV occurs 3 weeks after infection.^[3] In spite of vigorous donor screening, transmission of virus through blood transfusion cannot be avoided because during the window period, patient remains infectious and will not be detected by anti-HCV assay.^[4] During that phase, HCV RNA is the only diagnostic marker of infectivity and is the only tool of diagnosis in seronegative patients.^[3,4] Early identification of persons with chronic HCV infection would enable infected persons to receive the necessary care and treatment to prevent or delay the onset of liver disease.^[4]

In the absence of a vaccine for hepatitis C, the prevention of HCV infection depends upon reducing the risk of exposure to the virus. This is challenging because of the various routes of transmission and the different populations that are affected. Furthermore, the treatment is costly. In this scenario, donor screening remains one and only important tool for the primary prevention of HCV transmission.^[4] Furthermore, evaluation of the seroprevalence of HCV in healthy voluntary blood donors will give us a rough estimate of the disease burden in the general population.^[1] Furthermore, it gives the idea about the efficiency of blood transfusion services in preventing major TTIs like HCV. The objective of the present study is to assess the seroprevalence and the trend of HCV in healthy voluntary blood donors at a tertiary care hospital in Ahmedabad over a period of 3 years.

MATERIALS AND METHODS

Study design and patients

This is an observational, retrospective study carried out in the blood bank of a tertiary care hospital, Ahmedabad, Gujarat, India, to determine the prevalence of HCV among voluntary blood donors over a period of 3 years from January 1, 2017, to December 31, 2019. The blood collections were carried out from the voluntary donors at outdoor blood donation camps and in-house blood bank after screening as per the criteria based on technical manual for transfusion medicine by the WHO.^[2]

Inclusion criteria

Voluntary blood donors meeting the criteria based on technical manual for transfusion medicine by WHO.

Exclusion criteria

Voluntary blood donors not meeting the criteria based on technical manual for transfusion medicine by WHO and replacement blood donors.

After blood collection, 5 ml of donor blood was collected in a plain, sterile container for serological testing of TTIs.

A total of 9477 blood donations were screened for HCV using a commercially available 3rd generation enzyme-linked immunosorbent assay kit, the HCV Microlisa (J. Mitra and Co.) with reported sensitivity and specificity of 100% and 97.4%, respectively. The HCV Microlisa test utilizes a combination of both structural (Core, E1 and E2) and nonstructural antigens (NS3, NS4, and NS5) of HCV, which increases the specificity of the test. Tests were performed according to the manufacturer's instructions.^[7] All reactive samples were retested in duplication. Samples reactive in at least one of the repeated tests were considered positive. All the initial reactive and seropositive blood bags were discarded as per the National Biomedical Waste Management policies.^[8] Positive donors were requested to return to the blood bank for notification and consultation by trained physicians. The seropositive donors were permanently deferred,^[2] and the following algorithm suggested by the WHO [Figure 1] was followed for further diagnosis, monitoring, and treatment of chronic HCV infection.^[4]

Statistical analysis

The data were analyzed by calculating the frequency of HCV positivity. The Chi-square test and Chi-square test for trend analysis (Extended Mantel-Haenszel test for linear trend) were done to know the prevalence of HCV. $P < 0.05$ was set as the level of statistical significance. All the statistical

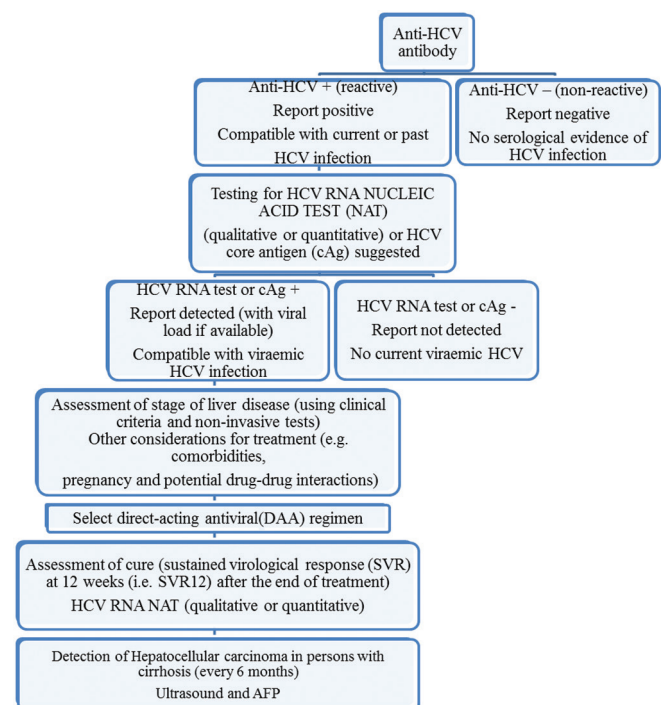


Figure 1: Algorithm suggested by the World Health Organization for hepatitis C virus infection

analyses were performed by the Statistical Package for the Social Sciences (SPSS) software trial version 19 (SPSS, IBM Company, Chicago, IL 60606, USA).

Ethical consideration

This study was approved by the Institutional Ethics Committee. Written consent was obtained from all the blood donors for blood donation and further serological testing for TTIs. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1975 Helsinki declaration, as revised in 2000.

RESULTS

In the present study, a total of 9477 voluntary blood donors were screened at the blood bank of a tertiary care hospital during the period of 3 years from January 1, 2017 to December 31, 2019. Of these, 9229 (97.38%) donors were males and 248 (2.62%) were females [Figure 2]. The dominance of males in blood donations as compared to females was statistically significant ($\chi^2 = 10.322$, $df = 2$ and $P = 0.005$).

Out of 9477 donors, ten (0.11%) were reactive for HCV during the study period. All seropositive donors were male.

Out of ten (0.11%) positive donors, six donors (0.07%) were within the age group of 21–30 years, followed by four donors (0.04%) within the age group of 31–40 years.

Seroprevalence of HCV shows a statistically significant decreasing trend (χ^2 for linear trend = 6.3, $df = 1$ and $P = 0.012$) over a period of 3 years [Figure 3].

DISCUSSION

Blood transfusion is a vital part of the modern medicine, but simultaneously, it carries the risk of transmitting transfusion

transmissible infections. An adequate and reliable supply of safe blood can be assured by a stable base of regular, voluntary, unpaid blood donors. These donors are also the safest group of donors as the prevalence of blood-borne infections is the lowest among this group.^[9] HCV is a leading cause of chronic blood-borne infection and chronic liver disease. The global epidemic of HCV infection emerged in the second half of the 20th century, and several lines of evidence indicate that it was primarily triggered and fed iatrogenically by the increasing use of parenteral therapies and blood transfusion. In developed countries, the rapid improvement of health-care conditions and the introduction of anti-HCV screening for blood donors have led to a sharp decrease in the incidence of iatrogenic hepatitis C, but the epidemic continues to spread in developing countries, where the virus is still transmitted through unscreened blood transfusions and nonsterile injections.^[10]

Table 1 depicts the comparison of gender-wise distribution in voluntary blood donation in different parts of the world. There is dominance of males over females in blood donations. As per the WHO fact sheet of 2020, globally, approximately 67% of the donated blood comes from male donors. However, out of 111 countries which report to the WHO, 14 countries receive <10% of the donations from females.^[9] In India, females are mostly anaemic and medically unfit for blood donation. Furthermore, Indian females are less educated, there is a fear of procedure, lack of awareness, and privacy issues which play a role in stopping females from donating blood. This can be improved by doing awareness programs and by providing privacy to females during blood donation. Family restrictions also play a role. Similar findings were seen in the other parts of the world.

Table 2 depicts the seroprevalence rate of HCV in the different parts of the world. The prevalence of HCV in blood donors in high-income countries ranges from 0.002% to 0.05%, in middle income countries ranges from 0.03% to 0.80%, and in low income countries, prevalence varies from 0.50% to 2.23%.^[9] The difference in seroprevalence of HCV from different regions might be due to the differences in epidemiological characteristics of the study population,

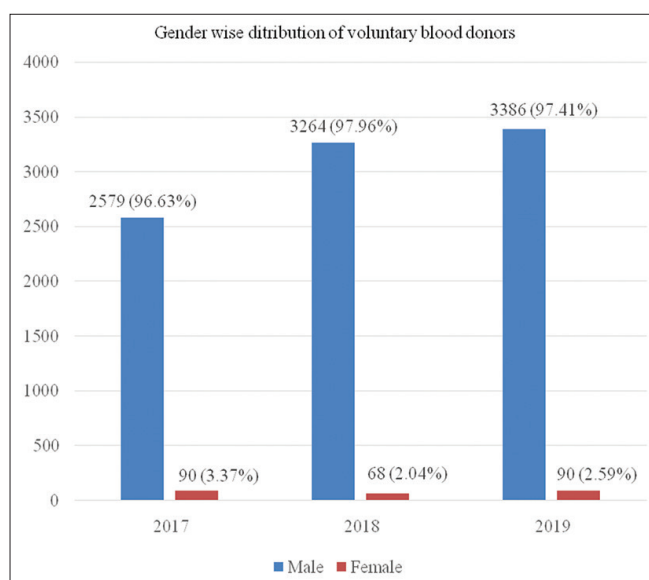


Figure 2: Gender wise distribution of voluntary blood donors in study population

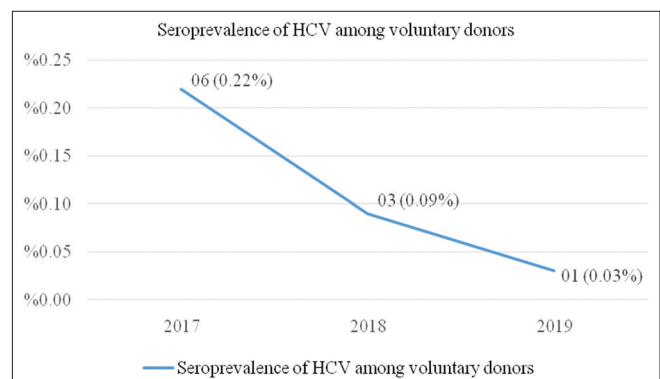


Figure 3: Year-wise trend of sero-prevalence of HCV among voluntary donors

Table 1: Comparison of gender wise distribution in voluntary blood donation in different parts of the world

Region	Male donors, n (%)	Female donors, n (%)	Total donors (n)
Central India ^[1]	58,816 (99.7)	182 (0.3)	58,998
West Bengal ^[11]	41,805 (89.1)	5095 (10.9)	46,900
Mumbai ^[12]	5120 (91.33)	486 (8.67)	5606
Pune ^[13]	16,972 (94.41)	1004 (5.59)	17,976
Ethiopia ^[14]	5118 (85.5)	865 (14.5)	5983
Nigeria ^[15]	509 (96.0)	21 (3.96)	530
Darjeeling ^[16]	25,517 (89.96)	2847 (10.04)	28,364
Pakistan ^[17]	3580 (98.08)	70 (1.92)	3650
Ahmedabad (present study)	9229 (97.38)	248 (2.62)	9477

Table 2: Comparison of hepatitis C virus seroprevalence rate in different parts of the world

Region	Seroprevalence (%)
Central India ^[1]	0.07
West Bengal ^[11]	0.12
Mumbai ^[12]	1.49
Pune ^[13]	0.21
Ethiopia ^[14]	0.6
Nigeria ^[15]	1.5
Darjeeling ^[16]	0.55
Pakistan ^[17]	1.04
Kenya ^[18]	0.3
Iran ^[19]	0.03
Ahmedabad (present study)	0.11

sample size and diagnostic techniques. Differences in type of donors (voluntary/replacement/professional) and educational status of the donors also play an important role. The period of time in which the studies were carried out is also an important parameter for the difference in seroprevalence. India is a middle-income country, and the seroprevalence of anti-HCV in voluntary blood donors in India has decreased in the 21st century compared to the 20th century.^[11] This decrease may be due to better screening protocols and diagnostic techniques.

Table 3 depicts the gender-wise distribution in HCV-positive voluntary donors in different parts of world. In all studies, most of the positive donors are male. However, in all these studies, female voluntary blood donors were very less in number and so we could not get a very correct idea about anti-HCV prevalence in female donors. This also implies that as more males opt for blood donation, seroprevalence is more in male donors. Furthermore, most of the recipients of blood and blood products are males so there is more risk of acquiring HCV infection in males and if they donate in future there is a risk of transmitting infection. Furthermore, males have high-risk behaviors much more than females such as having multiple sex partners, injection drug abuse, and homosexuality.

Table 3: Comparison of gender wise distribution in hepatitis C virus positive voluntary donors in different parts of the world

Region	HCV prevalence in males out of all positive donors, n (%)	HCV prevalence in females out of all positive donors, n (%)	Total positive donors (n)
Central India ^[1]	41 (100)	0 (00)	41
West Bengal ^[11]	52 (89.66)	6 (10.34)	58
Mumbai ^[12]	76 (90.5)	8 (9.5)	84
Pune ^[13]	36 (100)	0 (00)	36
Ethiopia ^[14]	89 (90.82)	9 (9.18)	98
Nigeria ^[15]	6 (75)	2 (25)	08
Ahmedabad (present study)	10 (100)	0 (00)	10

HCV: Hepatitis C virus

Table 4: Comparison of age-wise distribution in hepatitis C virus positive voluntary donors in different parts of the world

Region	Age group with highest HCV seroprevalence (years)
Central India ^[1]	31–40
West Bengal ^[11]	21–30
Mumbai ^[12]	21–30
Ethiopia ^[14]	21–30
Nigeria ^[15]	31–40
Ahmedabad (present study)	21–30

HCV: Hepatitis C virus

Table 4 depicts the age-wise distribution in HCV-positive voluntary donors in the different parts of world. The age profile of blood donors shows that, proportionally, more young people donate blood in low- and middle-income countries than in high-income countries.^[9] The risk of HCV infection in young age increment might be due to high-risk behaviors such as having multiple sexual partners, homosexuality, intravenous drug abuse, high prevalence of HIV (therefore, high HIV-HCV co-infection) are seen more among young age groups.

In this study, seroprevalence of HCV shows a statistically significant declining trend over 3 years. Similar finding was seen in a study by Mandal and Mondal.^[18] The decreasing trend may be due to increase in the awareness of general population about TTIs and better diagnostic techniques employed in recent years.

Despite following measures such as strict donor selection criteria, accepting only healthy voluntary donation and more sensitive diagnostic techniques, some transmission events are still possible because of the long window period, false-negative results, and other technical errors.

Early identification of persons with chronic HCV infection would enable infected persons to receive the necessary care and treatment to prevent or delay the onset of liver disease.^[4]

CONCLUSION

Each year, millions of lives worldwide are saved by blood transfusion. However, the awareness of both donors and recipients of risk associated with transfusion is less. Hepatitis C is a common cause of transfusion-related hepatitis. Universal access to safe blood transfusion requires the implementation of key strategies, including 100% quality-assured testing of donated blood, following WHO guidelines, conducting general promotion and awareness campaigns, organizing more camps, exclusive use of healthy voluntary blood donors, encouraging more women for blood donation, quality control checking, usage of more sensitive detection methods such as HCV antigen detection or nucleic acid amplification test, avoiding unnecessary blood transfusion and notification, counseling and treatment of reactive donors to ensure access to a safe and sufficient blood supply.^[2,4]

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Conflicts of interest

There are no conflicts of interest.

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