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Prevalence of Hepatitis C virus among voluntary blood donors of a blood bank in a mixed urban-rural setting in West Bengal, India

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***Abstract**: Background: Over 12 Million Indians Are Afflicted With Chronic Hepatitis C Infection, Says WHO. Prevalence Of HCV In Healthy Blood Donors Represents Prevalence Of Carrier State In The Population. High Rate Of Anti-HCV Antibody Positivity, Which Is Seen In Individuals Who Are Transfused Multiple Times, Is An Indicator Of Risk Of Contracting HCV By Blood Transfusion.*
Methods: All Voluntary Donors Reporting To The Blood Bank Were Screened For HCV Antibodies By Using The Appropriate Enzyme-Linked Immunosorbent Assay. The Study Was Designed For Duration Of Eight And A Half Years Between January 2010 To June 2018. Medical Reports Of The Donors Were Accessed From The Blood Bank Records And Analyzed.
Results: A Total Of 46,900 Voluntary Blood Donors Were Screened, Out Of Which 41805 (89.1%) Were Males And 5095 (10.9%) Were Females. The Seroprevalence Of Hepatitis C Was 0.12%.
Conclusion: Blood Borne Transmission Of Hepatitis C Virus Continues To Occur Despite Implementation Of Highly Sensitive Screening Tests For HCV, Suggesting These Assays Are Still Not Sensitive Enough To Prevent All Infections
***Keywords:** ELISA, Hepatitis C Virus, Voluntary Blood Donor*.

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I. Introduction

Hepatitis C virus (HCV) is a hepatotropic virus which was first discovered in 1989 as an important cause of transfusion associated hepatitis ("non-A, non-B hepatitis" or NANBH). It produces a slowly progressive liver disease, namely hepatitis, cirrhosis, and hepatocellular carcinoma (HCC). It is the most common cause of chronic hepatitis worldwide [1].

It is affecting over 170 million people (3%) world over. More than 3 million people are affected annually [1].

The genome of HCV is a single-stranded, positive-sense RNA molecule (++ss RNA) of approximately 9.6 kb in length. composed of a long open reading frame (ORF) flanked by untranslated regions (UTR's) at both the ends. The precursor is cleaved into at least 10 different proteins: the structural proteins: Core, E1, E2, and p7; as well as the non-structural (NS) proteins: NS2, NS3, NS4A, NS4B, NS5A, and NS5B. An important feature of the HCV genome is its high degree of genetic variability. The E1 and E2 regions are the most variable, while the 5'UTR and terminal segment of the 3'UTR are highly conserved. HCV has a high propensity for establishing chronic infection. [2] It has been estimated that in chronically infected people approximately 1012 viral particles are generated every day. This remarkable replicative rate in combination with the highly error prone polymerase activity of the virus results in tremendous genetic diversity and existence of various quasispecies within an infected individual.] HCV has been classified into six genotypes with multiple subtypes. Genotyping is recognized as the primary tool for assessing the course of infection and determining treatment duration and response. [3] The HCV antigen is of core variety.

The incubation period is 50–150 days. HCV spreads through blood, sexual activity when mixed with infected blood, and through the placenta. Using used needles during intravenous drug abuse and in unsafe healthcare setups are major risk factors. No vaccine is available against HCV[1].

. The present study was conducted to determine the prevalence of HCV antibodies in voluntary blood donors at a teaching hospital in Nadia district of West Bengal and to know the impact of a mandatory screening.

II. Materials And Methods

A retrospective hospital record-based study was conducted at the blood bank of a teaching hospital in Kalyani, District Nadia, West Bengal, India. The ethics committee of the institute approved the study. Data were collected for a period of 8.5 years from January 2010 to June 2016. Sera of voluntary blood donors from various localities and of different age groups was screened for HCV antibodies. A total of 46,900 blood units were collected and studied. All voluntary blood donors were screened as per WHO criteria for blood donor selection. Five millilitre blood was collected from each of the subjects into plain, sterile tube following informed consent. Blood samples were centrifuged, and the sera were separated and analysed. Two kits were used based on WHO recommendation of two different testing strategies involving enzyme-linked immunosorbent assay (ELISA) and/or simple or rapid assays for surveillance. Samples were analysed for antibodies to HCV, by 3rd generation ELISA. Any serum found reactive by the first assay was retested using a second assay based on different antigen preparations and/or different test principle using the anti-HCV test eg Nucleic amplifiticaon test (NAT). The validity of the test is assured as per the given criterion and the results were computed.

III. Results

In the present study, out of a total of 46,900 voluntary blood donors, 41,805 (89.13%) were males and 5095 (10.87%) were females which show predominance of males as compared to females for the eight and a half studied years [Table 1]. The prevalence of Hepatitis C (0.12%) among voluntary blood donors in the study population is showed in [Table 2].

The highest prevalence of Hepatitis C (51.72%) was noted within the age group 18-30 years, followed by 20.69% within the age group 31-40 years. [Table 3].

Sex distribution pattern of voluntary blood donors for Hepatitis C prevalence shown in [Table 4]. Prevalence of Hepatitis C is less in females as compared to males, but it is not statistically significant. ($p>0.05$)

IV. Tables

Table:1 Distribution of voluntary blood donors in the study population

Year	Total voluntary donors	Male	Female
2010	4531	4174	357
2011	4584	4267	317
2012	4970	4564	406
2013	4320	4002	318
2014	3530	3194	336
2015	4978	4469	509
2016	5269	4564	705
2017	9584	8209	1375
Upto June 2018	5134	4362	772
Total	46900	41805	5095

Table 2: Prevalence of Hepatitis C among voluntary blood donors in the study population

Year	Total no. of voluntary donors	Reactive for anti-HCV	
		Number	Percentage
2010	4531	3	0.07
2011	4584	3	0.07
2012	4970	5	0.10
2013	4320	6	0.14
2014	3530	0	0.00
2015	4978	1	0.02
2016	5269	10	0.19
2017	9584	20	0.21
Upto June 2018	5134	10	0.20
Total	46900	58	0.12

Table 3: Distribution of blood donors with anti-HCV according to age

Age (years)	Reactive for anti-HCV	
	Number	Percentage
18-30	30	51.72
31-40	12	20.69
41-50	8	13.79
51-60	8	13.79
Total	58	100

Table: 4 Distribution of blood donors with anti-HCV according to sex

Sex	Reactive for anti-HCV	
	Number	Percentage
Male (41805)	52 (0.124%)	89.66
Female (5095)	6(0.118%)	10.34
Total (46900)	58	100

V. Discussion

Hepatitis C virus (HCV) is the principal etiologic agent of post-transfusion hepatitis. The virus is distributed worldwide with prevalence varying from 0.2% up to 40% in different countries, which could lead to chronic hepatitis, cirrhosis, and even hepatocellular carcinoma [4]. Higher HCV prevalence have been reported in Southeast Asian countries, including India (1.5%), Malaysia (2.3%), Philippines (2.3%), Pakistan (8.1%), and in equatorial Africa (6.5%), as high as 20% in Egypt. [4]

In our study, the prevalence of Hepatitis C was found to be 0.12 %, while other studies like Giri et al [5] 0.74%, Pandit et al [6] 0.21%, Meena et al[7] 0.57%, Gupta et al [8]1.45% and Narayankar et al [9]1.49% noted higher prevalence. HCV seropositivity in the western part of India has been reported between 0.34 to 2.5% and another study done in Hissar, Haryana, the seroprevalence of anti-HCV antibodies was 1% [10]. A study done in Orissa reported anti HCV seroprevalence to be 1.98% [8]. The prevalence of hepatitis C in healthy blood donors was reported to be 1.09% in Punjab, 1.57% in Delhi, 0.75% in Madurai [3]. HCV Seroprevalence in Maharashtra among blood donors is 0.7% [6]. The seroprevalence rate of HCV among the blood donor population in India is 0.53 to 5.1% [8]. The probable reason of low prevalence in our study could be the partly rural setting of our study where risk of acquiring HCV is very low. More sensitive methods may be able to pick up more cases eg 4th generation ELISA and PCR-based methods.

Prevalence of Hepatitis C was highest in the age group of 18-30yrs (51.72%) followed by 31-40yrs (20.69%) in our study. A study from Punjab reveals highest prevalence (49.81%) of Hepatitis C infection within the age group 41-60 years, followed by 30.04% within the age group 21-40 years [10]. Another study from Delhi reported maximum seroprevalence of anti-HCV antibodies in the age group of 18 to 30 year (0.41%) [10] which was concordant to our findings.

Makroo et al [10] (2013) noted 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. In our study also male donors (0.124%) showed higher seroprevalence of anti-HCV antibodies compared to females (0.118%). A study from Pune showed a zero percent prevalence in females [6]. Similar findings were reported from Andhra Pradesh and Orissa. A report from West Bengal showed 0.59% seroprevalence in female voluntary blood donors [6]. Out of 104 countries which report to WHO, 18 countries receive less than 10% of the donations from females [6]. Lowest prevalence in females was observed in USA. But in all other studies, female VBD were very small in number and this prevented us from getting a very correct idea about anti-HCV prevalence in female donors. [6]

In the United States seroprevalence in HCV of blood donors was estimated to be 0.3 percent [11]. In Greece also, a low prevalence (0.2 to 0.4%) of antibodies to HCV has been reported and a similarly low rate (0.13%) was also reported from Iran. Lower rates of anti-HCV antibodies have also been reported in blood donors of Turkey (0.07%), Saudi Arabia (0.4%), Mexico (0.84%) and Kenya (0.9%) [11] . HCV is globally distributed, with anti-HCV prevalence among donors ranging from 0.3 to 0.5% throughout the world [6]. The World Health Organization estimates that the world-wide prevalence of HCV infection is approximately 3% [12].

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 [11]. 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 [11].

In India, mandatory blood screening for HCV is done by serological tests for antibodies to HCV. The screened seronegative donations are still at risk for HCV and thus, need for a more sensitive screening test arises to decrease this residual risk which has been reduced significantly over the last two to three decades in western countries where nucleic acid amplification test (NAT) has been implemented [13]. It is essential to follow up the anti HCV reactive blood donors on two accounts: first, for permanent deferral for blood donation and secondly, for early management of HCV infection [8]. People with known HCV infection should be counseled regarding ways to reduce the risk of transmitting HCV to others and means of minimizing their risk for HCV related complications [8].

VI. Conclusion

As no vaccine is available and as the treatment is expensive and prolonged, with a poor success rate, donor screening remains a key means of primary prevention of HCV transmission. Transfusion safety begins with healthy donors. A fundamental part of preventing transfusion transmitted infections (TTIs) is to notify and

counsel seropositive donors. Donor notification and counselling protect the health of the donor and his/her family members and prevent secondary transmission of infectious diseases. More sensitive tests to detect anti HCV antibodies and HCV RNA will help in detecting more cases of HCV infected blood and at an earlier stage, which will protect more recipients.

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