SEROPREVALENCE OF HEPATITIS C VIRUS AMONG BLOOD DONORS IN A TERTIARY CARE CENTRE IN KERALA

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ABSTRACT

BACKGROUND

Transfusion transmitted infections continue to be a threat to safe blood transfusion practices. The problems of window period is an important aspect in the detection of viral infections. Most persons infected with Hepatitis C are asymptomatic without any history of jaundice, but have chronic hepatitis with a few progressing to liver failure. Prevalence study helps to understand the depth of the problem in the community and also emphasises on more widespread use of newer diagnostic procedures to overcome the long window period in screening for Hepatitis C.

MATERIALS AND METHODS

This is a descriptive study conducted in the tertiary care settings of a Government Medical College in Kerala. Retrospective data pertaining to screening of blood units in the blood bank of the Institution during the study period from 2012 to 2016 were collected from the records and analysed to assess the prevalence of seroreactive Hepatitis C.

RESULTS

A total of 93,023 blood units were collected during the five-year period, of which 15,382 units were donated in outreach camps. Males were the predominant donors. There were 87,194 male donors during this period, while female donors accounted for 5829 units; 89% females donated in outreach camps. Most of the donors were in 18 - 40 years' age group; 67 samples were found to be seroreactive to Hepatitis C, of which only 2 were females. The overall prevalence of seroreactive Hepatitis C is 0.072%. Hepatitis C accounts for one-fourth of the total transfusion transmitted infections among blood donors.

CONCLUSION

Although, overall prevalence of Hepatitis C in this area is low, it is persistent and significant and contributes to a one-fourth of transfusion transmitted infections. Blood component use increases the risk of transmission of infection to multiple recipients. Transfusion of blood and blood components is a potential source of Hepatitis C. Since there are no currently available vaccines against Hepatitis C, transfusion safety is crucial for preventing the transmission of Hepatitis C.

KEYWORDS

Seroreactivity, Prevalence, Hepatitis C, Blood Donors.

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BACKGROUND

Transfusion of blood and blood products can lead to infectious and non-infectious complications in the recipients. Hepatitis C Virus (HCV) discovered in 1989 belongs to Flaviviridae family. It was previously known as Non A - Non B Hepatitis virus found associated with transfusion transmitted hepatitis. HCV is a lipid-enveloped, single-stranded RNA virus. The majority of HCV infections are asymptomatic. HCV is usually acquired by percutaneous exposure. High risk groups include intravenous drug users, transfusion recipients, transplant recipients, those using immunoglobulins, haemodialysis patients and healthcare workers.

Tattooing, acupuncture, use of unsterile needle for rituals and cultural practices, medical treatment and vaccination may result in transmission of HCV. HCV can be transmitted sexually and vertically from mother to child. Even though sexual and vertical transmission is uncommon, co-infection with HIV may increase transmission by these routes. HCV may also transmit to household contacts through percutaneous exposure.^{1,2,3}

Hepatitis C is distributed worldwide. Globally, Hepatitis C virus create a huge burden of disease in the form of chronic progressive liver diseases. Hepatitis C has become one of the major causes of liver cancer and one of the most common indication for liver transplantation. In 2015, an estimated 71 million people were living with chronic HCV infection according to WHO and only 20 percent of those infected with HCV had been tested to know the status. It is very important to study the prevalence of Hepatitis C in a population. There is a delay between the time an individual is exposed to an infection and the time the donor screening test for the infection becomes positive. Blood donated during this window period could transmit infection. Asymptomatic infection, carrier state, long incubation period and long window period create a real threat to transfusion safety.¹

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Blood donors represent a group of healthy people in a community. Prevalence among blood donors reflects the pattern of infection in general population. It is very important to screen all blood prior to transfusion for Hepatitis C. In India, The Drug and Cosmetic Act 1992 mandates the testing of each unit of blood for viral markers of Human Immunodeficiency Virus, Hepatitis B, Malaria and Syphilis. Mandatory testing for HCV antibody in blood donors started in 2001.⁴

Infectious disease screening of donors is accomplished by questioning of potential donors, exclusion of individuals with an increased risk of infection and testing of donor blood.

MATERIALS AND METHODS

The study was conducted in a tertiary care centre in Kerala, which is also a Government Medical College in Kerala. The study is a descriptive study based on retrospective collection of data from available records. The data was collected from the blood donor records and registers pertaining to the 5-year period from 2012 to 2016. All blood units collected in blood banks are tested mandatory for five diseases. Consent for testing was obtained from each donor prior to blood donation. Healthy blood donors were selected by a thorough screening process, which included a detailed history taking and physical examination. Donor screening process for infectious diseases involved a combination of donor education and self-deferral, donor questioning and testing. The donor serum samples were analysed to detect anti-HCV antibodies by third generation ELISA test. All the samples that were found positive by ELISA on initial testing were repeated in duplicate with the same samples. Samples that were found reactive on repeat testing were considered as positive and included in the study. Any equivocal or indeterminate samples were also discarded considering the safety of blood transfusion, but not included in the study. Seroreactivity to Hepatitis C virus is recorded in the respective screening register. Blood bank conducted outreach camps to promote voluntary blood donations. Outreach camps were conducted mainly in colleges, schools, offices, blood collection bus and other institutions. All the donor units collected during the study period in the blood bank as well as outreach camps were included in the study leading to a sample size of 93,023. Descriptive analysis was done on collected data. Estimation of total prevalence during the period was done along with the annual prevalence from the collected data to find out trends. The proportion of positive cases among male and female donors was estimated and Chi square test for proportions was done to find out any significant difference between them. The proportion of positive cases among total donors was also estimated for each year and a Chi-square test for proportions was done to find out any significant change in annual prevalence over the 5-year study period.

RESULTS

All the donor units collected during the study period from January 2012 to December 2016 by the blood bank were included in the study. The data was collected from the blood donor records and registers pertaining to the 5-year period from 2012 to 2016. A total of 93,023 blood units was collected during the study period. Blood was collected from donors who visited the blood bank and also from donors in

outreach camps conducted in colleges and other institutions. All the donations were voluntary in nature. Descriptive analysis was done on collected data. Out of 93,023 donors, 87,194 (93.74%) were males and 5829 (6.26%) were females. The distribution of donors according to their sex and place of donation is given in Table No. 1 and 2.

Year of Study	Male	Female	Total
2012	16595	565	17160
2013	15342	1023	16365
2014	16207	1656	17863
2015	18415	1644	20059
2016	20635	941	21576
Total	87194 (93.74%)	5829 (6.26%)	93023

Table No. 1. Distribution of Donors according to Sex

Year of Study	Blood Collected in Blood Bank			Blood Collected in Outreach Camps			Total (A+B)
	Male	Female	Total (A)	Male	Female	Total (B)	
2012	15409	110	15519	1186	455	1641	17160
2013	13392	72	13464	1950	951	2901	16365
2014	13807	71	13878	2400	1585	3985	17863
2015	16015	145	16160	2400	1499	3899	20059
2016	18387	233	18620	2248	708	2956	21576
Total	77010	631	77641 (83.46%)	10184	5198	15382 (16.54%)	93023

Table No. 2. Distribution of Donors according to Place of Donation

Of the total 93,023 units, blood collected from donors who donated in blood bank is 77,641 (83.46%) and outreach camps is 15,382 (16.54%).

The total number of male donors during this period was 87,194; of the male donors 88% (77,010) donated blood in blood banks, while out of 5829 females 5198 (89%) donated blood in outreach camps especially in colleges. Female donors were more in outreach camps. Total number of donors are also increasing every year showing more and more motivated young people are donating and also the increased demand for blood and blood products.

Females accounted for 5198 (33.8%) blood donations in outreach camps and only 631 (0.81%) blood donations in the blood bank. Thus, conducting more outreach camps promote female donations. 95% donors belonged to the age group 18 - 40 years.

The donor screening process involved a combination of donor education and self-deferral, donor questioning and testing. All samples were tested mandatory for five Transfusion Transmitted Infections (TTI), namely HIV antibody detection test, HBsAg antigen detection test and HCV antibody detection test, Malarial antigen detection test and Syphilitic antibody detection test. Screening tests used for Hepatitis C antibody detection was third generation ELISA kit. Repeatedly reactive samples are considered positive and included in the study. Any equivocal or indeterminate samples were also discarded considering the safety of blood transfusion, but not included in the study.

Out of 93,023 donor samples tested in five-year study period, 268 samples were found positive to Transfusion

Transmitted Infections (TTI); 0.29% is the prevalence of transfusion transmitted infections among blood donors during the study period.

In the total of 268 donor samples which were found reactive to these transfusion transmitted infections, of which 67 (25%) were due to Hepatitis C. Hepatitis C accounted for one-fourth of the total transfusion transmitted infections. This showed the magnitude of Hepatitis C among the transfusion transmitted infections (Table No. 3).

Year of Study	No. of TTI Reactive Donors	No. of Anti-HCV Reactive Donors
2012	41	2 (4.88%)
2013	32	2 (6.25%)
2014	79	27 (34.17%)
2015	52	15 (28.84%)
2016	64	21 (32.81%)
Total	268	67 (25%)

Table No. 3. Proportion of HCV Seroreactivity among all Seroreactive Samples

Transfusion transmitted infections were found more during the year 2014. A total of 79 cases. HCV seropositivity was also high during the year of 2014. Hepatitis C accounted for 34.17% of total TTI during the year 2014.

Hepatitis C seroreactivity among total donors is calculated to study the prevalence; 67 samples were found reactive to Hepatitis C antibody testing in the five-year period.

67 samples out of 93,023 donors showed positive reaction to Hepatitis C, thus giving an overall prevalence of 0.072% during the study period. The prevalence is 0.0746% among male donors and 0.0343% among female donors. There is no significant difference in the prevalence of Hepatitis C between male and female donors during the study period (Table No. 4).

	Male Donors	Female Donors	Total
Sero-Positive	65	2	67
Sero-Negative	87129	5827	92956
Total	87194	5829	93023

Table No. 4. Comparison of Sero-Positivity among Male and Female Donors (P value > 0.05)

During the study period, peak prevalence is observed during 2014 (0.1511%). A slight decrease in prevalence is obtained in 2015 (0.0747%). Again, a rise in prevalence is obtained in 2016 (0.0933%). Seroprevalence of Hepatitis C is too low in 2012 and 2013. Hence, we can see an increase in seroprevalence of Hepatitis C during the study period. There is a persistent trend and there is significant change in the yearly prevalence of Hepatitis C during the study period, (p value < 0.001).

The year-wise estimation of prevalence rates are given in Table 5 and Figure 1. It is clearly evident in the Figure that seroprevalence of Hepatitis C is increasing among blood donors and is persisting also.

Year	Total Number of Units Collected	Number of Samples Seroreactive to HCV	Prevalence
2012	17160	2	0.0116%
2013	16365	2	0.0122%
2014	17863	27	0.1511%
2015	20059	15	0.0747%
2016	21576	21	0.0933%
Total	93,023	67	0.0720%

Table No. 5. Yearly Estimate of Hepatitis C Prevalence (P value < 0.001)

Figure 1. Yearly Trend of Hepatitis C Prevalence

DISCUSSION

Transfusion of blood and blood products are increasing nowadays leading to the possibility of increased transfusion transmitted infections. Modern transfusion therapy guidelines also advocate component therapy. Thus, infectious agents in one donor may spread to multiple recipients. The problem of window period varies from few days to months depending on the infections and also the tests employed for detection. ELISA method for detection of antigen and antibodies are used widely throughout the country. Nucleic acid amplification tests ensure early detection of virus particles, but are used only in selected centres. Transfusion transmitted infections like HIV/AIDS are showing a decreasing trend nowadays, but the problem of Hepatitis C is increasing.

According to WHO, the most affected regions are WHO Eastern Mediterranean and European Regions with the prevalence of 2.3% and 1.5%, respectively. Prevalence of HCV infection in other WHO regions varies from 0.5% to 1.0%. Depending on the country, Hepatitis C virus infection can be concentrated in certain populations (for example, among people who inject drugs) and/or in general population. There are multiple strains (or genotypes) of the HCV virus and their distribution varies by region.¹

HCV has become one of the major causes of liver cancer and one of the most common indication for liver transplantation. There is a high rate of chronicity of about 15 - 85% following HCV infection. Most patients have asymptomatic infection with no history of jaundice, but have chronic hepatitis with some developing cirrhosis and few progressing to liver failure. Despite a low-to-moderate

prevalence of HCV, India accounts for a significant share of global HCV infections due to large population.^{1,2,3}

Studies from various part of the country showed a rise in prevalence of Hepatitis C. Long latent period for detection by screening tests is an issue that puts transfusion recipients under threat of acquiring Hepatitis C.

Various studies have been conducted to estimate the prevalence of Hepatitis C. The prevalence rate of anti-HCV seroreactivity was reported to be 1.44 in a study conducted from 1994 to 1999 in Trivandrum, Kerala.⁵ In a 10-year study conducted among blood donors in North India, Makroo et al found 0.39% donors reactive to HCV antibody detection tests. Seroprevalence of anti-HCV among males is 0.38% and that of females is 0.36%.⁶ No significant change in trend in the seroprevalence of anti-HCV antibodies was obtained in a 10-year period. The reactivity was maximum in 18 - 30 age group and decreases with age. A slight increase in the prevalence of HCV was noted by Makroo et al in a later study.⁷ The study found out that the risk of transfusion transmitted infections are decreasing with respect to HIV, Hepatitis B and Syphilis, but Hepatitis C is increasing.⁷

Prevalence of HCV among hospital-based population was alarmingly high at 7.7% in a study conducted in Andhra Pradesh, even though the study showed a decreasing trend in transfusion transmitted infections.⁸ A study conducted in Ludhiana showed a prevalence rate of 1.5%, which is similar to many studies conducted in India and other countries like Spain and Japan.⁹

In a study conducted in Vietnam, the prevalence of anti-HCV was 0.17%.¹⁰ This study reported a high prevalence of Hepatitis C in rural population. The study emphasises the need for Nucleic acid testing instead of ELISA for screening blood prior to transfusion. A study conducted on sickle cell patients in Uganda found HCV prevalence to be high among those receiving blood transfusion.¹¹ Blood transfusion is considered as a major contributing factor for transmission of Hepatitis C. This study concluded by saying that blood components prior to transfusion must be screened for Hepatitis C and transfusion dependent patients must also be screened for Hepatitis C.

Another study from Chandigarh showed HCV prevalence of 0.8%,¹² while a study from Bangladesh showed 0.17% seroreactivity among blood donors.¹³ Anti-HCV positivity showed wide range of fluctuation from 0.86% - 2.03% in a study reported from Punjab.¹⁴

A seroprevalence of 0.08% was found in a study conducted in central Kerala among 1200 blood donors, which is similar to the present study.¹⁵ The seroprevalence of Hepatitis C among donors was conducted in many centres and findings were similar to present study.^{16,17,18} The seroprevalence of Hepatitis C among donor population in India is 1.8% - 2.5%, and the community seroprevalence has been reported to be 0.87%.¹⁹ In another Kerala-based study by Sandesh et al the prevalence of Hepatitis C is 0.33% among voluntary blood donors, 0.12% in job seekers in Middle East Asia and 0.24% in normal population. IV drug abusers have also been found to have a high prevalence of anti-HCV antibodies.²⁰

South Kerala ⁵	1.44%
Central Kerala ¹⁵	0.08%
North Kerala ²⁰	0.33%

Present Study	0.072%
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Table No. 6. Comparison with Other Studies from Kerala

The prevalence of Hepatitis C is low in present study when compared to other similar studies. Refer Table No. 6. The donors were selected by trained medical staff after a careful history taking and physical examination. Counselling prior to donation, self-deferral by donors, exclusion of donors with high-risk behaviour and setting up a long deferral period for those with history of jaundice and history of contact with jaundiced patients reduced the seroprevalence.

Many seropositive donors did not give a history of hepatitis in the past on retrospective enquiry. Some remembered history of hepatitis in close friends, in hostel and at home. Few gave history of hospitalisation and injectable drugs usage during their stay in other parts of India. All these suggest asymptomatic infection with Hepatitis C. Even though it is very essential to screen all transfusion recipients for Hepatitis C, only a minority is exposed to transfusion. Common modes of spread of infection in community is unsafe injections, dental procedures, sharing of needles in intravenous drug abuse, unsterile medical procedures, tattooing, skin piercing, etc. Infection is seen more in those with high-risk behaviour. Co-infection with HIV and other hepatitis may lead to chronic carrier state.

Like other studies, males were the predominant donors in blood banks. Female donors were donating in outreach camps. Conducting more outreach camps promote voluntary blood donation and female participation. Voluntary blood donation ensures safe blood to an extent.

Need for blood and blood products are increasing. Blood collection was increasing yearly during the study period. Transfusion transmitted infections were also showing a rising trend with peak number obtained in 2014. ELISA is a highly sensitive test and difference in the sensitivity of ELISA kits used alters seroreactivity. All seropositive cases have to be confirmed by repeating antibody screening after an interval of three months and other nucleic acid tests.

In the present study, Hepatitis C prevalence is estimated over a five-year period with a peak value obtained in 2014 and coming down in 2015 and 2016. Male donors started ear piercing and tattooing during this period. It is essential to screen for Hepatitis C in those who had done skin piercing and tattooing. Even though the prevalence in the present study is low, it accounts for 25% of the total transfusion transmitted infections among blood donors during the study period.

Effective screening tests are required to prevent transmission of Hepatitis C to transfusion recipients. Newer techniques such as Nucleic acid amplification test for Hepatitis C RNA should be employed for screening blood samples prior to transfusion and can increase transfusion safety. It is also an ethical imperative to provide more widespread availability of such tests, so that only safe blood components are transfused.

Limitations of the Study

The study is a record-based data collection. Different kits were used for testing anti-HCV antibodies at different point of time. Third generation ELISA kits were used. Sensitivity and specificity might vary with manufacturers.

CONCLUSION

Hepatitis is emerging as an important infectious disease worldwide. Transfusion transmitted Hepatitis, especially Hepatitis C is an important public health problem as it is asymptomatic with a long incubation period and chronicity. The demand on blood products are increasing daily. Component therapy increases the risk of transferring infections to multiple recipients. In spite of the low prevalence, the infection shows a rising trend in the number of seroreactive cases in recent years. There is presently no vaccine available for preventing Hepatitis C and the only recourse is to raise transfusion safety. Strict donor recruitment process, proper history taking, predonation counselling, promoting voluntary blood donation, testing for anti-HCV antibodies all reduce the chance of transfusion-transmitted hepatitis. Nucleic acid detection tests surely reduce the window period and aids in effective screening for Hepatitis C. The present study emphasises the need of newer diagnostic aids in the detection of Hepatitis C.

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