ASYMPTOMATIC CHRONIC CARRIER - A POTENTIAL HAZARD TO BLOOD RECIPIENTS -BLOOD BANK-BASED STUDY

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ABSTRACT

BACKGROUND

Blood transfusion is an effective mode of transmission of hepatitis C infection. Hepatitis C is an emerging infection in India, which was detected in 1989. US and Japan started screening for HCV in 1990, which was mandatory and in India in 2002. Despite testing of blood units, HCV infection is still a significant problem. HCV is transmitted through blood and its components.

MATERIALS AND METHODS

The present study was conducted to detect hepatitis C in blood donors (voluntary and replacement donors) for two years and screening done by ELISA (3rd generation UBIR, HCV EIA.4-0 kit).

RESULTS

Seroprevalence of anti-HCV in 14,727 donors was 0.33%. Coinfection with HCV was observed in 3 donors of HBsAg and 1 donor of HIV seropositivity. Large number of donors were from urban areas (66.66%) and seropositivity among them was 0.36% and from the rural areas (33.34%) with seropositivity of 0.15%.

CONCLUSION

In conclusion, the present study has established the prevalence of HCV antibody in healthy donors was 0.29% in our area (Davangere). This proves that compulsory screening for HCV lowers the incidence of Post Transfusion Hepatitis (PTH).

KEYWORDS

HCV, Hepatitis C Virus, Seroprevalence, Blood Donors, ELISA.

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BACKGROUND

The transmission of infectious disease through donated blood is of concern to blood safety as blood transfusion forms an integral part of medical and surgical therapy.

The patient receives the blood from innumerable private and government blood banks situated all over the country. The blood banks are finally responsible for the supply of safe blood products.¹ The Department of Drug Controller have enforced screening for Hepatitis C Virus (HCV) a mandatory to prevent the post transfusion hepatitis.

Hepatitis 'C' is a major global public health problem.² As very little data is available in Indian literature, it is very essential to undertake the study to determine the prevalence of HCV antibody in healthy Indian donor population.³

Hepatitis 'C' occurs throughout life particularly in adulthood and the incidence is higher than Human

Financial or Other, Competing Interest: None. Submission 18-03-2017, Peer Review 24-03-2017, Acceptance 06-04-2017, Published 07-04-2017. Corresponding Author: Dr. Rukmini Sudhakar, Plot. No. B1, Opp. Government Quarters, Santosh Nagar, Hubballi-580032. E-mail: rukminihaveri@gmail.com DOI: 10.18410/jebmh/2017/328 Immunodeficiency Virus (HIV). The HCV positive donors are known to be viraemic, which is an indication for compulsory screening of all the blood and blood products for HCV infection.⁴

Reinfection

Some individuals infected with HCV experience, multiple episodes of acute hepatitis raising the possibility of reinfection with HCV or of reactivation of original virus infection. Super infection with heterologous HCV indeed occurred in chronic hepatitis patients who were infected with different HCV genotype after transfusion with contaminated blood. In multitransfused haemophiliacs, frequent reinfection of HCV is observed.

Moreover, recurrent infection of HCV occurs in patients who receive liver transplants or liver grafts after liver transplantation. The HCV genome mutates frequently in an infected host and thus neutralising antibody for the preexisting virus may not recognise a new variant. Alternatively, immunity after HCV infection maybe too ineffective to recognise a challenge by the same virus.

HCV infection occurs in 2 to 8 percent of infants born to HIV infected mothers. This risk increases if the mother is also HIV infected or if the maternal level of HCV RNA is high because of passive transfer of maternal antibodies.



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The risk of transmitting HCV infection to the recipient from donor is about 1 in 10, 3000 donations.⁵

The seroprevalence of HCV in India varies from 0.3% in the North to as high as 11.3% in the South in general population.⁶ Anti-HCV screening is very effective in reducing prevalence of post transfusion hepatitis in India.⁷ Asymptomatic chronic carrier is a potential hazard to the blood recipient. It is conclusively proved that Enzyme-Linked Immunosorbent Assay (ELISA) screening of blood unit for hepatitis C infection is highly effective.

It is very important to study the prevalence of HCV infection in a healthy blood donor population as it plays a role in the pathogenesis of chronic active hepatitis and cirrhosis of liver. The risk of suffering from Hepatocellular Carcinoma (HCC) is almost definite though it happens many years after transfusion. Diagnostic tests for HCV were developed soon after identification of HCV.

HCV infection is usually diagnosed by testing for HCV antibodies in serum with an enzyme immunoassay that includes recombinant HCV proteins. Second and later generations of these antibody assays are highly sensitive screening tools.

The average period for diagnosis for HCV seroconversion after blood transfusion has been shortened with each new generation tests, 7-8 week for ELISA-3, 10 weeks for ELISA-2 and 16 weeks for ELISA-1.⁸

There is no vaccine available against this virus, which makes the situation graver. Moreover, the value of specific antiviral therapy with interferon is unproven. To analyse this, we must first examine the available prevalence data in healthy donor population.⁹ The currently available UBI, HCV EIA4.0 is used to detect antibodies, which employs synthetic peptides for the detection of HCV antibody in human sera or plasma.

This study is conducted to find the prevalence of HCV antibodies in healthy donors with an aim to provide safe blood for transfusion.

Aims and Objectives

1. To know the prevalence of HCV among blood donors.

2. To evaluate the efficacy of 3rd generation ELISA kits in screening for HCV antibodies.

MATERIALS AND METHODS

Source of Data

The population screened constituted healthy, voluntary and replacement donors who donated blood at blood bank of Bapuji Hospital, Davangere. Blood bank of Bapuji Hospital, Department of Pathology, J.J.M. Medical College is licensed blood bank with average collection of 14,727 units of blood from healthy donors from in and around Davangere annually.

The blood samples were subjected to HCV screening by ELISA 3rd generation kit. The blood samples were tested as per drugs and cosmetic act and screening for HCV is studied in detail.

Method Employed

The kit used is UBI^R HCV EIA4.0 manufactured by Beijing United Biomedical Co., Ltd., Beijing, PR China.

Detection of Antibody to HCV

The serum samples were processed for antibody by using 3^{rd} generation ELISA kit developed by Beijing United Biomedical Co., Ltd., Beijing.

The kit contained synthetic peptides to highly segments of core, NS3, NS4 and NS5 regions of HCV. The tests were performed and interpreted following the manufacturer's instructions.

Detection of antibody in the serum sample was carried out in an automated ELISA reader (Flex Tek_2^{TM}) using UBI^R , HCV EIA4.0 kits.

The Flex Tek_2^{TM} is a fully automated laboratory processing unit working in conjunction with specifically designed Microsoft Windows 95^{TM} software. This system can process most EIA microplate assays by operations that are automatic and programmable Flex Tek^{TM} enables the user to perform multiple analysis faster and more accurately.

Procedure (automatic dilution directly in the microplate)-

Required number of microplates were taken and 200 μ L of specimen diluent followed by 10 μ L of specimen or control were dispensed into them.

They were covered and incubated for 30 minutes at 37^oC. The microplates were washed with wash buffer (6 washes with automatic microplate washer).

100 μ L of the working conjugate solution was added to wells of microplates and incubated for 15 minutes at 37°C. Washing procedure was repeated, then 100 μ L of OPD substrate solution was added to each well and incubated for 15 minutes at 37°C.

100 μ L of stop solution was added each well and absorbance was read at 492 ± 2 nm (within 1 hour after the addition of stop solution).

RESULTS

The presence or absence of antibody specific for HCV was determined by relating the absorbance of the specimens to the cut-off value.

For the assay to be valid, the absorbance difference between the means of the ANTI-HCV STRONGLY REACTIVE and ANTI-HCV NON-REACTIVE CONTROLS (SRC-NC) should be 0.400 or greater.

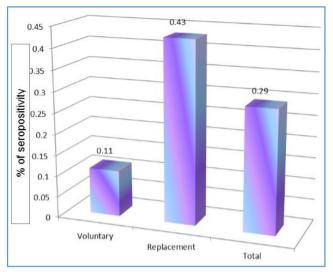
The present study is undertaken to know the prevalence of HCV antibody in healthy blood donors in the blood bank of Bapuji Hospital, J.J.M. Medical College, Davangere.

Total number of donors screened during the study period of two years were categorised into voluntary donors and replacement donors who constituted 43.39% and 56.61%, respectively.

Total Donors	HCV Positivity	Seroprevalence	
14,727	43	0.29%	
Table 1. Seroprevalence in Blood Donors			

Among the total donors 14,727 the HCV antibody reactive donors were 43 with a seroprevalence of 0.29%.

The seroprevalence among replacement donors was 0.43% when compared to voluntary donors 0.11%.



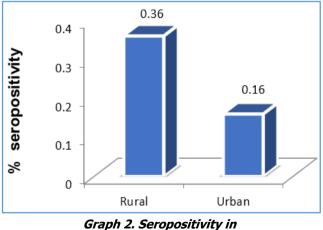
Graph 1. Seropositivity in Different Types of Donors

Infection	Voluntary Donors	Replacement Donors	Percentage	
HBsAg	-	3	0.02	
HIV	-	1	0.01	
Table 2. Dual Infection in Total Donors				

The study showed 3 donors to be positive for HBsAg along with HCV positivity constituting 0.02% and one donor showed positivity for HIV and HBsAg along with HCV positivity (0.01%).

Total	Urbai	Rural		
Donors	Davangere	Other District	Areas	
14,727	6,203	3,614	4,910	
Table 3. Geographic Distribution in Total Donors				

In the present study, the urban population constituted 66.66% of total donors with 33.34% being from rural areas.



Relation to Residence of Donors

Among 43 HCV positive donors, urban population constituted 0.36% and 0.16% donors were from rural areas.

		Seropositivity			
	Total	Voluntary Donors	Replacement Donors	Total	%
Urban	9,817	5	30	35	0.36
Rural	4,910	2	6	08	0.16
Total	14,727	7	36	43	0.29
Table 4. Seropositivity in Relation to Residence of Donors					

DISCUSSION

The study was undertaken to determine the seroprevalence of HCV antibody among healthy donors in the blood bank, Bapuji Hospital, J.J.M. Medical College, Davangere. The total number of donors screened for HCV antibody by the ELISA kit of 3rd generation was 14,727.

HCV is one of the transfusion transmissible infection. The prevalence of which varies in different parts of the world from 0.04 to 26%. It is very important to study the prevalence in healthy blood donor population as it plays an important role in the pathogenesis of chronic active hepatitis and cirrhosis of liver. The risk of patient suffering from hepatocellular carcinoma is definite though it happens several years after transfusion.

As there is paucity of data of HCV infection from Indian literature, this study is undertaken to know the seroprevalence among healthy donors in and around Davangere.

Report	Prevalence Rate	
French group	0.68%	
Spanish group	1.2%	
German group	0.42%	
USA group	0.36%	
Japan group	1.5%	
Present study	0.29%	
Table 5. Seroprevalence in Different Parts of World		

Most of the Indian studies report a seroprevalence of 0.2% to 4% in blood donor's population. The seroprevalence of HCV in our study among 14,727 donors is 0.29%, which can be compared with USA group and study of Deshpande Anand where the seropositivity was 0.36% and 0.34%, respectively.

This varied incidence maybe because of the size of the blood donor population studied.

G. Sood ¹⁰ (1992)	1.8%	
V.A. Arankalle ¹¹ (1995)	2.5%	
SPB Jaiswal ¹² (1996)	1.7%	
Deshpande Anand ² 1998	0.34%	
R.N. Makroo ¹³ (1999)	0.53%	
H. Kaur ⁴ (2001)	0.7%	
Mathai Jaisy ¹⁴ (2002)	1.4%	
Menon M and Iyer Ranganathan ⁵ (2002)	0.76%	
Present study	0.29%	
Table 6. Seroprevalence in Different Parts of India		

Voluntary Donors

The blood donors of this category constituted 43.39% showing the seropositivity of 0.11%. This relatively low seropositivity in voluntary blood donors is also observed in other studies.

Replacement Donors

The replacement donors constituted about 56.61% showing prevalence of 0.43%. The prevalence is quite high in other studies.

Low level of test positivity in our study may be attributed to proper precounselling of patient on arrangement of blood donors, coordination between blood bank and user departments, facilitates planning and providing sufficient time for procuring blood. Provisions for emergency needs are met with ready availability of screened blood. These strategies effectively check hasty recruitment of blood donors and ensures effective selection of donors. Proper education, motivation of the student community is crucial in preventing the transmission of these deadly infections.

From the observations made in our study, the overall seroprevalence for a total sample of 14,727 screened was 0.29%.

Total Number of Donors	Voluntary Donors	Seropositivity %	Replacement Donors	Seropositivity %	
Mathai Jaisy, 31,942(94-99)	7.04%	-1.70%	90%	-2.50%	
Jaiswal (1996)	35.48%	1.78%	-	1.78%	
Arnakalle (1995)	21.50%	0.23%	-	0.23%	
Present study, 14,727(2004)	43.39%	-0.11%	56.61%	-0.43%	
Table 7. Seroprevalence in Total Donors					

CONCLUSION

It has been established that the incidence of post transfusion hepatitis C infection decreased considerably after screening the blood for antibody by third generation ELISA tests.

However, the risk of transmission of HCV cannot be eliminated completely even after anti-HCV testing. In case, blood is donated by an asymptomatic donor during the window period, when antibodies cannot be detected either because of the production of the antibodies has not yet started or the antibody levels are so low that the assay cannot detect them.

As per national policy, the major thrust is on voluntary blood donation and phasing out of replacement donations. Motivations and recruitment of potential local donor population as a first step would lead to an effective voluntary system in the long run and pave way for centralised transfusion services with increase in blood safety.

Expansion of donor selection criteria, uniform testing facilities for TTI along with HCV will help to target, low risk donors. This along with well-informed donor base would go a long way in bringing down transfusion transmitted infections in the recipient. Co-infection of HBsAg and HCV will be responsible for development of HCC.

In conclusion, the present study has established the prevalence the HCV antibody in healthy donors was 0.29% in our area (Davangere). This proves that compulsory screening for HCV lowers the incidence of Post Transfusion Hepatitis (PTH).

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