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Research Article

DEMOGRAPHIC DETERMINANTS AND TRENDS IN SEROPREVALENCE OF HEPATITIS C VIRUS IN HEALTHY BLOOD DONORS

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ABSTRACT

Background: Hepatitis C virus is now widely recognized as one of the common etiological agents for cirrhosis of liver. The prevention and control of HCV infection shows complexity and challenge in describing geographic distribution of HCV infection and determining its associated risk factors. This study aims to provide a data on the demographic characteristics that determine the risk for HCV infection among blood donors, so as to help make prevention strategies and guide further research.

Objective:

1. To determine the prevalence rate of HCV antibodies in replacement and voluntary blood donors.
2. To study the demographic determinants among HCV sero-positive donors

Methodology: A total of 3099 blood units collected during 2012 were mandatorily screened for HCV infection using third generation Microlisa. A retrospective data analysis was done on the healthy blood donors and information collected on demographic variables.

Results: Out of the total 3099 donors, 58.7% (1819) were replacement donors and 41.3% (1280) were voluntary donors. The overall sero-prevalence of HCV was 0.35% among the donors. The prevalence showed a declining trend. The significant demographic determinants were age, gender and educational status of donor.

Conclusion: Awareness and education of the community to increase voluntary blood donation as they form a safe source of blood supply. Identification of determinants may help to curtail the spread of HCV infection in the population. There is a need for more stringent donor selection criteria based on the determinants in addition for a safer blood supply from blood banks.

Keywords: Voluntary blood donor, Hepatitis C virus, Anti-HCV, Prevalence, Determinants, Trends.

INTRODUCTION

Blood transfusion is a lifesaving intervention that has saved millions of lives worldwide. But it carries a potential risk of transmitting infections. It is one of the most common transmission pathways of hepatitis C virus (HCV). This risk is minimized by selection of healthy donors after detailed history, examination, counseling and mandatory screening procedure of blood units before transfusion. Transfusion related transmission of infections is a matter of concern to the physicians, patients and the policy makers as the risk is not zero.

HCV along with hepatitis B virus (HBV) is responsible for the majority of post transfusion hepatitis. It was first detected by a group of collaborating scientists from Chiron and the Centre for Diseases Control[1]. HCV infection is an important health problem in many countries. According to a review, 3 percent of the world's population or almost 200 million persons are infected with HCV[2]. Acute HCV infection is usually asymptomatic, but the chronic infection is life-long and may lead to cirrhosis, chronic liver disease and hepato-cellular carcinoma. HCV accounts for one fourth of all cases of chronic liver disease in India. It is estimated that there are 12.5 million HCV carriers in India[3]. The global seroprevalence of HCV among the blood donors ranged from 0.1–19.2 percent[4]. In India, the seroprevalence of HCV in voluntary blood donors in different parts ranged between 0.12 - 4 percent[5, 6, 7]. This geographical variability of HCV seroprevalence can be explained by the extent to which different risk factors contribute to the transmission of HCV infection. The safety of blood transfusion is compromised because of improper screening of the donors. Also in many circumstances, availability of blood units is largely dependent on replacement donors. The other factors compromising the safety may be

lack of trained personnel, lack of funds, cost of screening and endemicity of hepatitis. Voluntary blood donors are generally considered to be healthy and safe for blood donation and can be considered a mirror reflection of the situation in the general population. The prevalence of HCV has fallen globally from 1992, after mandatory screening of blood for HCV as documented in Japan and US[8]. Mandatory screening for HCV was introduced in India as late as 2002, which also showed a significant decline in the prevalence of HCV. The studies from different parts of India reveal that despite of mandatory screening of blood units, HCV is still a significant problem for patients who are recipients of multiple blood transfusions. Only few population based studies have been carried out systematically in India[9]. Most of the prevalence studies are based on blood donors with an assumption that voluntary donors are healthy and are a surrogate for the general population. However with increased dependency on replacement donors and professional donors the results may not be the true picture. Many studies have looked at the risk factors for causing HCV infection. Very few studies have identified the demographic determinants of HCV sero-positivity among blood donors, but none from this part of India. It is also important to study the prevalence, age distribution and risk factors for causing HCV infection among the donor population to ensure transfusion of safe blood to the recipient. This will help to minimize the risk of transmission of HCV infection and will help to incorporate necessary changes in the donor questionnaire at the time of donor selection. This knowledge might give us the idea of disease burden and help in further understanding the basic epidemiology of HCV in the community. Hence a study was undertaken to find out the prevalence of sero-positivity of HCV and its determinants among healthy blood donors.

MATERIALS AND METHODS

The study is a retrospective analysis of the data available at the blood bank under the Department of Pathology, Navodaya Medical College, Raichur, Karnataka. The approval for the study was obtained from the Institutional Ethics Committee. The demographic data of blood donors were obtained and reviewed from the records of the blood bank from January 2012 to December 2012. Voluntary blood donors donate their blood without any pressure and monetary benefit for unknown recipients. Replacement blood donors are the members of family, relatives or friends of the patients, who donate their blood in replacement of the blood needs of the particular patients. Replacement donation is a common practice in our country and mostly seen at tertiary care hospitals. Repeat voluntary blood donors are included with a gap of at least three months interval in between the two blood donations. A total of 3099 healthy blood donors, both voluntary and replacement had donated their blood during this period as per the data available at the blood bank. The blood units after collection were screened for mandatory tests like HIV, HCV, HBsAg, VDRL and for Malaria. Before collection, donors were selected and screened thoroughly. The details of the healthy donors were recorded in the form after counselling. All the procedures were done as per the guidelines of the routine blood donation screening procedure. The test procedure for HCV was done as per the recommended procedure of Microlisa (J. MITRA & CO. PVT. LTD, NEW DELHI, INDIA). Presence of HB_s Ag in collected blood was detected with SD HBsAg ELISA 3.0 (STANDARD DIAGNOSTIC, INC). HIV I and II rapid assay of collected blood was done with Microlisa ELISA (J. Mitra and Co. Pvt. Ltd.). The 3rd generation HCV Microlisa is based on highly sensitive technique, Enyme Linked Immunosorbent Assay (ELISA) which detects against HCV in human serum and plasma. The HCV proteins are present in the serum at level well below the limits of detection. Thus immunodiagnosis of HCV infection is based on detection of host generated antibodies (anti-HCVs) to viral proteins. The 3rd generation HCV Microlisa utilizes a combination of antigen with the sequence of both HCV structural and non-structural antigen i.e CORE, E1, E2, NS3, NS4, and NS5. It has an obvious advantage over the available 2nd generation ELISA with improved sensitivity and specificity. The test had a sensitivity of 100 % and specificity of 97.4 %.

The potential donors gave their consent to test blood for screening and declared it as voluntary donation. The demographic information regarding age, gender, education, occupation and address were recorded on the form. Also information regarding risk factors like history of surgery, blood transfusion, hospitalisation, tattooing, ear piercing, high risk behaviour and fever was taken. In addition, the form contained questions to exclude unhealthy donors. All the samples reactive for HCV were repeat tested before being labeled as sero-positive. Data were entered in Microsoft Excel and analyzed using SPSS version 17.0 statistical software. Mean, proportions, and standard deviation were calculated depending on type of data. All statistical tests were two-tailed, and results were considered significant at $p < 0.05$.

RESULTS

The total blood units screened at the blood bank was 3099. Out of this, 1280 (41.3%) were voluntary donors and remaining 1819 (58.7%) were replacement donors. Mean age of the donors was 27.0 years and mean number of blood donations was 1.3. The total donors found reactive for anti HCV antibodies were 11, giving an overall sero-prevalence of 0.35 percent. With regards to co-infection, none of the anti HCV reactive donor was found positive for HIV infection. Only 1 donor was found to be co-infected with HCV and HBV infections. The prevalence of HCV infection among voluntary donor was slightly less (0.31%) as compared to replacement donors (0.38%). Trend analysis revealed that the proportion of HCV positive donors significantly decreased over time in both type of donors. The demographic determinants studied were age, gender, educational status, marital status, religion, occupation and number of blood donations in past.

HCV infection rate of individuals aged 20 - 30 was 0.7% , while the prevalence rate among individuals above 31years was 0.2%, and this association was significant statistically($p < 0.05$). The present study has investigated the association between the prevalence rate of HCV infection and gender among blood donors. HCV infection rate of male blood donors

was 0.5% and showed a significant statistical difference between males and females. HCV sero-prevalence rate were higher among the illiterate (0.7%) as compared to literates (0.2%). This also showed a statistically significant association between them. The prevalence of HCV infection was higher among the donors who were unemployed (1.0%) and unskilled (0.4%) by occupation as compared to donors who were skilled by occupation (0.2%). But it was not statistically significant. Though the prevalence was higher among never married donors than ever married donors, but was not significant. The donors were grouped into Hindus and non-Hindus for analysis and the difference in HCV infection was not statistically significant ($p < 0.05$). The prevalence among first time donors was the highest (0.6%) than among repeat donors. This difference also was not statistically significant. HCV infection rate among voluntary blood donors and replacement blood donors were 0.3 % and 0.4% respectively. There was no significant statistical difference. All these findings are depicted in table 1. The comparison of the findings of HCV sero-prevalence in the present study which was 0.35% showed wide variations with the prevalence rates quoted by other studies from India. This comparison of HCV prevalence between present study and other studies from India indicate much diverse prevalence of this deadly infection as shown in table 2. The prevalence of HCV and HBV co-infection was found to be 9 % in the present study.

Table 1: Demographic determinants of HCV infection among healthy blood donors

Variables		HCV sero-positive	HCV sero-negative	X^2 value	P Value
Age in years	20-30	8 (0.7)	1210 (99.3)	5.17	< 0.05*
	> 31	3 (0.2)	1878 (99.8)		
Gender	Male	11(0.5)	2168 (99.5)	4.66	< 0.05*
	Female	0 (0.0)	920 (100.0)		
Educational Status	Illiterate	6 (0.7)	815 (99.3)	4.41	< 0.05*
	Literate	5 (0.2)	2273 (99.8)		
Occupation	Skilled	3 (0.2)	1321 (99.8)	2.95	> 0.05
	Unskilled	6 (0.4)	1567 (99.6)		
	Unemployed	2 (1.0)	200 (99.0)		
Marital status	Never married	7 (0.6)	1125 (99.4)	3.49	> 0.05
	Ever married	4 (0.2)	1963 (99.8)		
Religion	Hindu	9 (0.5)	1827 (99.5)	2.33	> 0.05
	Non-Hindu	2 (0.2)	1261 (99.8)		
No. of previous blood donations	0	6 (0.6)	1011 (99.4)	2.42	> 0.05
	1-2	3 (0.2)	1382 (99.8)		
	> 2	2 (0.3)	695 (99.7)		
Type of donor	Voluntary	4 (0.3)	1276 (99.7)	0.11	> 0.05
	Replacement	7 (0.4)	1812 (99.6)		

*** Significant**

Table 2: Comparison of HCV Sero-prevalence among healthy blood donors between present and other Indian studies

S. No	Author & Place of study	Study period	No. of donors	Prevalence of HCV
1	Pahuja et al. [28] 2007, New Delhi	2002-2005	28,956	1.01%
2	Bhattacharya et al. [29] 2007, West Bengal	2004-2005	106695	0.35%
3	Thakral et al. [5] 2006, Chandigarh	2001-2002	16250	0.44%
4	Gupta et al. [30] 2004, Punjab	2001-2003	44064	1.09%
5	Arankalle et al. [31] 1995, Maharashtra	-	2726	0.7%
6	Garg et al. [32] 2001, Rajasthan	1999- 2004	46957	0.29%
7	Das et al. [33] 2002, Tamil Nadu	-	22245	1.4%
8	Zeenath Begum et al. [34] 2013, Gulbarga, Karnataka	2003-2012	7066	0.18%
9	Present study	2012	3099	0.35%

DISCUSSION

Blood transfusion is a potentially significant route of transmission for transfusion transmitted infections. Hence, availability of safe blood for transfusion is a must for the recipients. Prevalence of HBV, HCV, and HIV among the healthy blood donors or the replacement donors reflects the disease prevalence in the community. It also estimates the risk of chance of acquisition of these infections during blood transfusion. Transmission of HCV is primarily through blood

exposure, and majority progresses to chronic infection and chance of cirrhosis and hepatocellular carcinoma is more than HBV.

In different Indian studies[10-14], HCV seroprevalence ranged between 0.57 to 1.49%, which was much higher than the present study (0.35%). The differences in HCV sero-positivity is also seen globally due to differences in donor base and the risk factors that are prevalent in the donor population. This also implies that the determinants of acquiring HCV infection may vary from region to region as also suggested by Mathai et al[15] in their study from Kerala. Low sero-positivity for diseases in our study could be attributed to proper counseling of blood donors and donor selection criteria followed by rationale use of blood.

The higher prevalence of HCV among males compared with females may be attributed to risk factors associated with male activities. Also it was noted that the prevalence of HCV was higher among the age group less than 30 years of age. This is in contrast with the findings of other studies[16, 17] where the prevalence increased with age that can be explained by increased exposure with age. Similar findings were reported by Jain et al[18] with maximum prevalence rate of 1.8% in the age group of 20-29 years with decreasing trend with increasing age.

HCV sero-prevalence was more in replacement donors as compared to voluntary donors which is similar to other studies from India[5, 11]. It is said that voluntary donors are safer than replacement donors as they are aware of the risk of transmission of infections and understand better. Replacement donors may conceal the information regarding their health and sexual history as they donate blood under compulsion with a fear that they may be rejected as donors. No difference was observed between first time donors and repeat donors. The findings are similar to other study from North India [19] and by Retrovirus Epidemiology Donor Study (REDS) group[20]. Hence efforts to be made to educate the community for more voluntary blood donation for safe blood supply.

Among the demographic variables, educational status of donors was a significant determinant with illiterates having a high prevalence of 0.7% than literates. This association of education with HCV sero-positivity of donors may be suggestive of involvement of social factors rather than biological susceptibility as suggested by Akhtar et al[21]. The other demographic variables like occupation, marital status and religion of the donors were insignificant determinants and are in accordance with other studies[22, 23]. In our study, prior history of blood transfusion was not significantly associated with HCV sero-positivity among the donors. Similar results were reported by Deshpande et al[24]. A study from rural Vietnam[25] also reported a low prevalence of hepatitis B and hepatitis C co-infection in potential blood donors similar to the present study.

The determinants identified by the present study could help the local blood bank personnel in the deferral of blood donors who are likely to be sero-positive to HCV infection. Hence primary level of prevention should also focus on identified risk factors to curtail the spread of HCV in the present and other similar settings. Also there is an urgent need to adopt newer sensitive technologies for detection of HCV infection in window period as the present ELISA kits used in the blood banks in India do not detect HCV before 82 days of infection[26]. Stringent measures need to be taken for blood donor screening that includes the identified determinants and by using more sensitive methods to detect infections early, like Nucleic acid amplification technology (NAT) assays[27].

CONCLUSION

HCV would be responsible for emerging infection in India whose long-term implications will be felt in the future. Educating people and creating awareness about voluntary blood donation is an important part of prevention. People are unlikely to become voluntary donors unless they receive accurate information about blood. For this voluntary blood donation camps have to be enc ouraged and the practice of replacement donor has to be discouraged. The need for better prevention by health education and screening for HCV in collaboration with public health authorities becomes mandatory. The present study has highlighted the need for further research to identify more determinants for HCV infection among healthy donors and also in general population.

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