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HEPATITIS C VIRUS SEROPREVALENCE IN TRANSFUSION-DEPENDENT THALASSEMIC/ HEMOPHILIC PATIENTS AT SMS HOSPITAL AND ALLIED HOSPITALS

Dr. Bhupendra Kumar Mandawat*

Associate Professor, Department of Microbiology, Government Medical College, Kota (Rajasthan).

***Corresponding Author: Dr. Bhupendra Kumar Mandawat**

Associate Professor, Department of Microbiology, Government Medical College, Kota (Rajasthan).

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ABSTRACT

Hepatitis C virus (HCV) poses a serious public health problem due to its global prevalence. Hepatitis C virus is considered to be the main aetiological agent responsible for the occurrence of post-transfusion hepatitis. Patients with thalassemia and hemophilia acquire hepatitis most often from viruses contracted through blood transfusions. **Background:** HCV is the commonest cause of post transfusion hepatitis accounting for nearly 80-90% of cases. More than 200 million carrier of HCV exist in the world and constitute the reservoir of this infection. The carrier rate of HCV infects ranges from 10-20%. Since year 1991 Screening of blood for HCV antibody in blood banks has been made mandatory in many parts of world. In India screening of blood for HCV Antibodies become mandatory from 1st July, 1997(10). **Objectives:** The present study was undertaken to evaluate the prevalence of hepatitis C virus (HCV) in thalassemic /hemophilic patients with multiple blood transfusions. This study is conducted to aid in early detection & treatment & its prevention of HCV Virus infection in thalassemic/hemophilic patients. **Methodology:** The present study was conducted in the clinical microbiology laboratory of the S.M.S. Hospital, Jaipur from period of 1st January, 2007 to 13th November 2007 to evaluate the prevalence of anti HCV Antibody in thalassemic /hemophilic patients. RAPID Test and ELISA TEST was done at clinical microbiology laboratory S.M.S. Medical College & Hospital, Jaipur. **Result:** In Our present study, Out of 250 sample tested for thalassemic /hemophilic patients, 2(0.8%) were positive for anti HCV antibodies. Total no. of 250 samples was tested, out of which 227 samples of thalassemic patients and 23 of hemophilic patients. Out of 227 samples of thalassemic patients, 2(0.88%) were positive for anti HCV antibodies and Out of 23 samples of haemophilic patients, none case(0%) were positive for anti HCV antibodies. HCV seroprevalence was maximum in 21 – 30 years age group (40%) and 0.64% in 0 – 10 year age groups and Out of 145 males patients, 2 (1.37%) were positive for anti HCV antibodies and out of 82 females patients, none were positive for anti HCV antibodies in thalassemic patients. **Conclusions:** HCV infections are prevalent among transfusion-dependent thalassemic /hemophilic patients in India. Nevertheless, seroprevalence decreased significantly and dramatically for HCV after universal blood screening.

KEYWORDS: Hcv, Thalassemia, Haemophilia, Rapid Test, Elisa Test.

INTRODUCTION

Hepatitis C virus (HCV) is the major cause of post-transfusion hepatitis infection (PTH). Transfusion-dependent subjects, such as patients with thalassemia and hemophilia, are at a great risk of viral acquisition. The virus infects liver cells and causes severe inflammation in liver with long-term problems.[20] Infection with HCV may lead to disabling symptoms, cirrhosis and hepatocellular carcinoma.[7,16] It is said that from 2010–2019, HCV may cause to the loss of 1.83 million years of life among people less than 65 years of age.[23] WHO studies show that, 170 million of people are infected by HCV in the world.[9] Thalassemia/ haemophilia is an inherited blood disorder. Patients with thalassemia/ haemophilia major are at high risk of hepatitis C due to the blood transfusion from donors infected by HCV.[3] Although, improvement in screening of blood products from 1980 to 1990 decreased the risk of transmission of blood-borne diseases, however, hepatitis C is still remained as an important problem in patients with thalassemia /haemophilia.[13,14] Chronic post transfusion hepatitis C lead to hepatocellular necrosis, fibrosis and cirrhosis in patients with thalassemia/ haemophilia and accepted as an important cause of morbidity and mortality in these patients.[2] Hepatitis C virus is a pathogen causing significant mortality & morbidity throughout the world including India. A spontaneous HCV clearance rate of 28-42% has been reported among thalassemic and hemophilic patients in the West.[24]

AIMS AND OBJECTIVE

The present study was undertaken to evaluate the prevalence of hepatitis C virus (HCV) in thalassemic/hemophilic patients with multiple blood transfusions in different individuals from different OPDS, thalassemic and hemophilic ward, other ward and ICUs of SMS Hospital and Allied hospitals. This study is conducted to aid in early detection & treatment & prevention of HCV Virus infection in thalassemic /hemophilic patients.

MATERIAL AND METHODS

The present study was conducted in the clinical microbiology laboratory of the S.M.S. Hospital, Jaipur from period of 1st January, 2007 to 13th November 2007 to evaluate the prevalence of anti HCV Antibody in symptomatic and asymptomatic individuals of Thalassaemia/Haemophilic patients. Various patients were identified based on clinical evaluations & various investigations.A totals of 250 blood samples were collected from the outdoor and indoor patients of S.M.S. and its allied hospitals. The collected blood was allowed to clot & serum was separated. The sample were stored at 2-8^{0}c & tested within 7 days of collection. Patients' serum samples were subjected to following tests for detection of Anti-HCV antibodies.

A-Rapid test: - DOT immunoassay for detection of Anti-HCV antibodies.[11,15]
B- Elisa test:- For Detection of Anti-HCV antibodies.[8,17]

HCV Microelisa Test: The 3rd generation HCV Microlisa is an in vitro qualitative enzyme linked immunosorbent assay for the detection of antibodies against HCV (anti-HCVs) in human serum or plasma. This kit is manufactured by J. Mitra & co. Pvt. Ltd. New Delhi, India.

Principle:- The 3rd generation HCV Microlisa is based on a highly sensitive technique, Enzyme Linked Immunosorbent Assay which detects antibodies against HCV in human serum and plasma. 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.The results were read on Microplate spectrophotometer at 450 nm. Cut off value was calculated as per the manufacturer's guidance and the results were interpreted accordingly. Cut off value = 0.1xPCx+0.1, PCx = Mean absorbance of positive control Interpretation:- According to their absorbance values, samples were interpreted as either reactive for HCV antibody (HCV positive) or non reactive for HCV antibody (HCV negative) if test specimens with absorbance value within 10% below the cutoff should be considered suspect for the presence of antibodies and should be retested in duplicate. Sample found to be reactive initially by HCV Microlisa test were again tested by visual rapid test which is HCV TRI-DOT test.

HCV TRI-DOT:- The 4th Generation HCV TRI-DOT is a rapid, visual, sensitive and qualitative in vitro diagnostic test for the detection of antibodies to Hepatitis C Virus in human serum or plasma. They are for the putative core (structural), protease/helicase NS3 (non-structural) NS4 (non-structural) and replicas NS5 (non-structural), regions of the virus in the form of two test dots "T_1" & "T_2" to provide a highly sensitive and specific diagnostic test. This Kit is manufactures by J. Mitra & Co. Pvt. Ltd. New Delhi, India.

Principle:- 4thgeneration HCV TRI-DOT has been developed and designed using modified HCV antigens representing the immunodominant regions of HCV antigen. HCV antigens are immobilized on a porous immunofiltration membrane. Interpretation: - Results are noted as per manufactures guidelines and results were interpreted accordingly. If test dots T_1, & T_2, either both dark and light in colour (pink), result should be considered reactive for antibody to HCV. If only control dot appear it indicates that the sample is non-reactive for anti-body to HCV. Sample found to be positive for HCV antibodies by both HCV Microlisa test & HCV TRI-DOT method would be further tested for hepatitis B Surface antigen by ELISA test.

Bio-Safety**:-**All standard precautions, bio-safety measures & biomedical waste managements in our study according to Biological waste management's Rules 1998 were observed.

RESULT

Total no. of anti HCV antibody positive cases in our study were low 0.8% in thalassemic /hemophilic patients. In Our present study, Out of 250 sample tested for thalassemic /hemophilic patients, 2(0.8%) were positive for anti HCV antibodies. Total no. of 250 samples was tested, out of which 227 samples of thalassemic patients and 23 of hemophilic patients. Out of 227 samples of thalassemic patients, 2(0.88%) were positive for anti HCV antibodies and Out of 23 samples of hemophilic patients, none (0%) case were positive for anti HCV antibodies. HCV seroprevalence was maximum in 21 – 30 years age group (40%) and 0.64% in 0 – 10 year age groups and Out of 145 males patients, 2 (1.37%) were positive for anti HCV antibodies and out of 82 females patients, none were positive for anti HCV antibodies in thalassemic patients. Comparison of studies conducted by other researchers showed slight variations in prevalence of HCV infection. There is a scarcity of information on HCV prevalence particularly in developing countries like India, hence present study was conducted for early detection & prevention in thalassemic/hemophilic patients.

Table 1: HCV SERO Prevalence Among Thalassemic/Hemophiliic Patients.

Transfusion-dependent risk group patients	Total No. of sample tested	Total No. of HCV (+) cases
Thalassaemia/Hemophilia patients	250	2 (0.8%)
Total Number of Cases	**250**	**2 (0.8%)**

This table shows that shows HCV seroprevalence among thalassemic /hemophilic patients. Out of 250 sample tested for thalassemic/hemophilic patients, 2(0.8%) were positive for anti HCV antibodies.

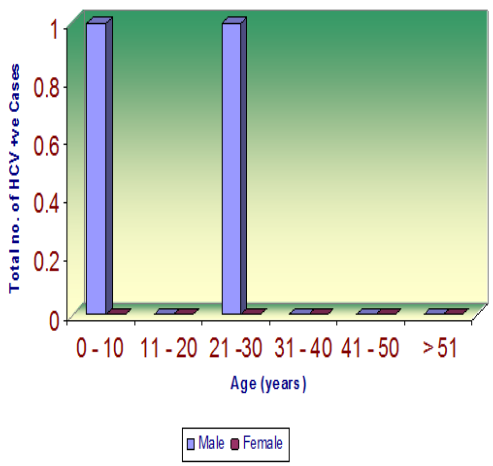
Table 2: Age Wise And Sex Wise Distribution Of Hcv Seroprevalance In Thalassaemic And Hemophilic Patients.

Age in Year	Thalassaemia				Hemophilia				Percentage (%)
	Male		Female		Male		Female		
	Total no. of tested	Total no. of HCV Positive	Total no. of tested	Total no. of HCV Positive	Total no. of tested	Total no. of HCV Positive	Total no. of tested	Total no. of HCV Positive	
0-10 yr.	91	1 (1.09%)	61	0	2	0	0	0	**1/154 (0.64%)**
11-20 yr.	40	0	19	0	12	0	0	0	0/71 (0%)
21-30 yr.	14	1 (7.14%)	2	0	9	0	0	0	**1/25 (40%)**
31-40 yr.	0	0	0	0	0	0	0	0	0
41-50 yr.	0	0	0	0	0	0	0	0	0
>51 yr.	0	0	0	0	0	0	0	0	0
Total No. of Cases	**145**	**2 (1.37%)**	**82**	**0**	**23**	**0**	**0**	**0**	**2/250 (0.8%)**

Total No. of Cases	MALE+ FEMALE	Total no. of HCV Positive	Percentage (%)	MALE+ FEMALE	Total no. of HCV Positive	Percentage (%)	2/250 (0.8%)
	227	**2**	**0.88%**	**23**	**0**	**0%**	

Tables shows Total no. of 250 samples were tested out of which 227 samples of thalassemic patients and 23 of haemophilic patients. Out of 227 samples of thalassemic patients, 2(0.88%) were positive for anti HCV antibodies and Out of 23 samples of hemophilic patients, none (0%) case were positive for anti HCV antibodies**.** HCV seroprevalence was maximum in 21 – 30 years age group (40%) and 0.64% in 0-10 year age groups. Tables also show out of 145 males patients, 2 (1.37%) were positive for anti HCV antibodies and out of 82 females patients none were positive for anti HCV antibodies in thalassaemic patients.

Age Wise and Sex Wise Distribution of Hcv Seroprevalance In Thalassaemic Patients



DISCUSSION

The prevalence of anti-HCV seropositivity has geographical variations ranging from 0.02% to 22% worldwide. Hepatitis C virus (HCV) is the major cause of post-transfusion hepatitis infection (PTH). Transfusion-dependent subjects, such as patients with thalassemia and hemophilia, are at a great risk of viral acquisition.[20] Thalassemia/ haemophilia is an inherited disorder. Patients with thalassemia/ haemophilia major are at high risk of hepatitis C due to the blood transfusion from donors infected by HCV(3). Chronic post transfusion hepatitis C lead to hepatocellular necrosis, fibrosis and cirrhosis in patients with thalassemia/ haemophilia and accepted as an important cause of morbidity and mortality in these patients.(2) We demonstrated that anti-HCV seropositivity in transfusion-dependent patients (thalassemic /hemophilic patients) currently remains low in our study. However, the rate of HCV infection decreased dramatically after universal blood screening.Our finding is supported by various other studies done in other parts of the world and India.

Table 3: Comparative study on HCV Seroprevalnce in Thalassaemia / Haemophila Patients.

S. No.	Authors & Year	Thalassaemia	Haemophilia
1	Battacharya et al 1991[6]	14.3%	25
2	William et al 1992[22]	11.1%	-
3	Amarapurkar et al 1992[5]	17.5%	-
4	Weiland O. et al 1992 (Italy)[21]	70%	-
5	Aggarwal MB et al 1993[3]	16.7%	-
6	Narang et al 1994[12]	3.8%	-
7	Jaiswal et al 1995[19]	25.45%	-
8	V.A. Arankalle et al 1995[18]	5.66%	-
9	A. Chakrawati et al 2005[1]	60%	-
10	Present Study (2007)	0.88%	0 %

Our findings are in accordance with various authors as above. The prevalence of HCV among thalassaemia and haemophilic in present study were 0.88% and 0% respectively. The prevalence of HCV among thalassaemia and haemophilic has been reported from 3.8% to 70%. It was 14.3% in Battacharya et al 1991 study, 11.1% in William et al 1992 study, 17.5% in Amarapurkar et al 1992 study, 16.7% in Aggarwal MB et al 1993 study, 25.45% in Jaiswal et al 1995 study and 60% in A chakrawati et al 2005 study in various regions of India. The prevalence was low 5.66% in VA Arankalle et al 1995 (Western India) and 3.8% in Narang et al 1994 (North India). In haemophilic patients, very few studies have been undertaken around the world. In India, prevalence of HCV among haemophilic patients was 25% in Battacharya et al 1991 study. In the present study, it was 0.88% and 0% in thalassaemia and haemophilic patients respectively. It may be low due to the National blood policy prepared in 1984 for many blood banks in India for providing safe blood required for transfusion and probably because currently we are using 4th generation anti-HCV kits which is the most sensitive technique for detection of anti-HCV anti bodies than the past time which could be the reason for the increased rate of HCV infection.

SUMMARY AND CONCLUSION

The present study was conducted in the Department of Microbiology & Immunology, SMS Medical College, Jaipur The object was assessing the seroprevalence of anti HCV antibodies in thalassemic/hemophilic patients at SMS and Allied Hospitals.

In all, 250 patients were screened. The observations were made with reference to age sex, constitutional symptoms, and investigations.

- The seroprevalence of HCV has declined since the screening of blood for donation in blood banks for anti HCV antibodies became mandatory in 1991 in some parts of the world and in India since 1997.
- HCV infection prevalence varies with geographical distribution and social characteristic of population groups.
- We demonstrated that anti-HCV seropositivity in transfusion-dependent patients (thalassemic /hemophilic patients) was 0.8%. Total no. of 250 samples were tested, out of which 227 samples of thalassemic patients and 23 of haemophilic patients. Out of 227 samples of thalassemic patients, 2(0.88%) were positive for anti HCV antibodies and Out of 23 samples of haemophilic patients, none (0%) case were positive for anti HCV antibodies. HCV seroprevalence was maximum in 21 – 30 years age group (40%) and 0.64% in 0 – 10 year age groups and Out of 145 males patients, 2 (1.37%) were positive for anti HCV antibodies and out of 82 females patients, none were positive for anti HCV antibodies in thalassemic patients.
- This study also evaluated risk factors for HCV infection among thalassemic /hemophilic patients. Our study is a step ahead in this direction with the purpose of providing authentic scientific data based on the affected population attending our hospital. The regularised national blood policy followed by blood banks for providing safe blood along with better screening method of donated blood in blood banks would bring down the incidence of hepatitis C in such high risk group.
- In conclusion, thalassemic/hemophilic patients are at risk of acquiring HCV infection and progression to liver failure and hepatocellular cancer. Therefore, blood donor screening protocol and effective screening techniques are likely to be needed to prevent speared of HCV infection among thalassemic/hemophilic patients. HCV infection is the most important cause of chronic hepatitis in several countries of the world. But at present no vaccine is available for it. Because of the increasing prevalence rate, this is necessary that medical personnel and health care workers must be educated and trained about the danger and consequences of HCV infection. All anti HCV antibody positive patients must be considered highly infectious and must be prohibited from donating blood, organ, tissues or semen. Therefore, routine screening of all the blood donors should be done in Blood Bank.
- We conclude that HCV directly affects epidemiology, morbidity, mortality, socioeconomic and preventive aspects. It is very important that the priority for HCV control is concentrated on early detection and effective treatment of both HCV and

HBV of which may offer the greater chance of prolonging the life of those suffering from HCV infection. It is suggested that education of public at large to increase the general awareness towards the transfusion transmitted diseases and how to prevent them. The prevalence of HBV and HCV co-infection is definitely present in the general population as is shown by the present study, the extent of which may vary from region to region and the study group screened. Both viruses contribute to the development of a chronic liver disease entity complementing each other during the progressing pathology. Reusage of unsterilized, contaminated needles and syringes were perhaps the main reason determined for the spread of HBV and HCV or both. This calls for stringent screening measures for blood borne viruses at departmental laboratories and blood banks for all sera/blood processed.

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