

Clinical Spectrum, Molecular Assay and Genotyping of Hepatitis C Virus in a Tertiary Care Centre of Northern India

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ABSTRACT

Chronic hepatitis C virus (HCV) infection is a pan-global public health problem; our cross-sectional study over one year in 100 HCV-Ab positive patients whose mean age was 44.9 years showed predominance between 31 and 40 years. Genotype 3 was the most prevalent but maximum viral load was seen in genotype 1. Genotype 3 is most difficult to treat, hence it will be difficult to achieve a high sustained virological response with treatment.

Introduction

Viral hepatitis is public health problem in India and globally, and is important because of its morbidity & mortality. Its seroprevalence is 2.8%, corresponding to >185 million infections worldwide (MOHFW, 2018; Petruzzello *et al.*, 2016). In India there are 12 million people with HCV infection with a mortality of 37,000 deaths noted in the year 2015. There are six distinct major and one minor genotype. As HCV replicates rapidly, it constantly changes and mutates, thus making it difficult to develop a long-lasting vaccine (MOHFW, 2018). Genotyping helps in investigating outbreaks, understanding its epidemiology and virological features.

Accurate analysis of data related to efficacy and resistance of new HCV drugs, implementation of therapeutic procedures, is important as is improvement of diagnostic tests (MOHFW, 2018). HCV genotypes 1 and 3 are the two most prevalent genotypes in India and globally, and account for 76.3% cases worldwide (Shah *et al.*, 2016). HCV causes both acute and chronic hepatitis, the latter leading to cirrhosis in >20% (MOHFW, 2018). The risk of hepatocellular carcinoma (H.C.C) in cirrhosis is 2–4% per year (WHO). WHO aims at a 90% reduction in new cases of chronic HCV infection, a 65% reduction in HCV deaths, and treatment of 80% of eligible people with chronic HCV infection (WHO, 2016). The ultimate goal of HCV treatment is to

achieve a significant sustained virologic response rate (SVR) by interfering with HCV replication (MOHFW, 2018). Better understanding of chronic HCV infection is key.

Materials and Methods

A cross-sectional study over one year was carried out in the departments of Microbiology and Gastroenterology, Pt. B.D. Sharma Post Graduate Institute of Medical Sciences (PGIMS), Rohtak. A total of 100 HCV-Ab positive patients were included in our study. Included were patients >18 years confirmed to have HCV infection on Anti-HCV antibody & HCV RNA testing and willing to participate by giving informed consent. Excluded were pregnant women, and co-infection with HBV & HIV.

The HCV viral load & genotypes and their correlation with clinical signs and symptoms were analysed using the latest version of SPSS software; comparison between categorical variables was computed using Fisher's exact test. A p value < 0.05 was considered statistically significant.

Results and Discussion

The following observations were made:

The majority of patients were married as the most common age for having chronic HCV infection in our study group is between 20-40 years and in our country by this age normally also people get married. It also emphasizes the need of screening of partner of the infected patients for preventing sexual transmission.

The mean viral load ranges from 1.5×10^4 - 1.6×10^5 . There was a statistically significant difference seen for the values between the groups ($p < 0.01, 0.05$) with higher values in 1.

Countries with the highest reported prevalence rates are located in Africa and Asia (Shepard *et al.*, 2005) and distribution of HCV genotypes varies substantially in different parts of the world (Yabaji *et al.*, 2018). Thus, the present study was planned to determine clinical spectrum and genotyping of Hepatitis C virus in a tertiary care hospital. The age distribution curve showed a sharp peak in the age group 31 to 40 years. The highest prevalence of chronic HCV patients is seen in Rohtak as Nodal Treatment Center is located here and majority of patients are referred to PGIMS for HCV assessment and treatment (Verma *et al.*, 2014). 80% of the HCV patients were asymptomatic, detected at screening camps followed by during preanesthetic checkups for surgeries and blood donation, as observed globally (Chung, 2005). In the present study various probable source of infection are injections by the local RMP, piercing and tattooing, h/o surgery & blood transfusions. Genotype 3 was most prevalent genotype constituting 63% followed by genotype 1 in 21% patients and Genotype 4 in 16% of the study population. It is pertinent to prepare a policy of screening population at a younger age. Also, in order to control the spread of HCV infection the awareness among the population needs to be highly emphasized in National Viral Hepatitis Control Program (NVHCP). Viral genotype and viral load are two important prognostic variables, knowledge of which might be useful in the treatment decisions.

Table.1 Demographic profile

Age (years)	31-40	25%
Marital status	Married	87%
Sex ratio	Males	60%
Chief complaints	Asymptomatic	80%

Table.2 Distribution of various genotypes in the study population.

Genotype	Number of Patients	Percentage Subtype
1	21	21% 1a: 6%, 1b: 13% 1c :2%
3	63	63% 3a: 44%, 3b:19%
4	16	16% 4a: 8%, 4b: 8%

Table.3 Distribution of study population according to genotype and chief complaint.

Chief complaint	Genotype			Total
	1	3	4	
Asymptomatic	18	48	14	80
Fever only	1	4	0	5
Generalised weakness	0	5	0	5
Fever, vomiting	0	2	1	3
Gastric upset	0	2	0	2
Indigestion only	1	0	0	1
Joint pain only	0	1	0	1
Joint pain & Pain abdomen	0	0	1	1
Pain abdomen & Diarrhoea	0	1	0	1
Skin allergy, rash	1	0	0	1
Total	21	63	16	100

Table.4 Distribution of study population according to genotype and age group in years (n=100)

Genotype	Age groups						Total
	18-30	31-40	41-50	51-60	61-70	>70	
1	3	8	4	3	2	1	21
3	12	13	18	10	8	2	63
4	3	4	2	3	3	1	16
TOTAL	18	25	24	16	13	4	100

Table.5 Distribution of study population according to source of infection and genotype. (N=100)

Source of infection	Genotype			Total
	1	3	4	
H/o injection with a needle by a local RMP	7	34	5	46
H/o piercing and tattoos	11	21	7	39
H/o intravenous drug use	3	2	0	5
H/o Surgery	10	21	8	39
H/o organ transplant	1	0	0	1
H/o blood transfusion	4	12	5	21
H/o unprotected sex	1	5	1	7

Table.6 Distribution of study population according to viral load seen in different HCV genotypes.

Genotype	Patients	Mean HCV-RNA	P-Value
1	21	16.0×10^4 IU/ml	0.01
3	63	1.5×10^4 IU/ml	>0.05
4	16	4.1×10^4 IU/ml	>0.05
Total	100	6.7×10^4 IU/ml	

Viral load seems to be a valuable predictive marker for the outcome of antiviral therapy since alanine transaminases (ALT) levels do not necessarily reflect disease activity. In the present study the maximum viral

load has been observed in the patients infected with genotype 1 followed by genotype 4 and least has been seen with genotype 3.

The HCV infection is seen maximally in asymptomatic young males. In symptomatic patients, generalized weakness and fever are most common presentation. Genotype 3 was the most common genotype prevalent in all age groups and associated with all the risk factors. Genotype 3 is most difficult to treat and has been associated with a higher rate of complications, including fatty liver disease, fibrosis, hepatocellular carcinoma and mortality, thus SVR achieved in this group is less than as seen in other genotypes.

Author Contributions

Pushkar: Investigation, formal analysis, writing—original draft. Paramjeet Singh Gill: Validation, methodology, writing—reviewing. Parveen Malhotra:—Formal analysis, writing—review and editing.

Data Availability

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethical Approval Not applicable.

Consent to Participate Not applicable.

Consent to Publish Not applicable.

Conflict of Interest The authors declare no competing interests.

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