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HCV Genotype and Viral Load Distribution among Infected Patients at a Tertiary Care Center in Western Uttar Pradesh

Shivangi Gupta[1], Dr. Sudhir Singh[2]

[1]Research Scholar, Department of Microbiology, Teerthanker Mahaveer Medical College and Research Centre, Teerthanker Mahaveer University, Moradabad (U.P.), 244001, India.
[2]Professor, Department of Microbiology, Teerthanker Mahaveer Medical College and Research Centre, Teerthanker Mahaveer University, Moradabad (U.P.), 244001, India.
Research Scholar - ORCID ID 0009-0006-6628-4247, Professor - ORCID ID 0009-0007-5090-4592
Corresponding Author- Shivangi Gupta Gmail ID: shivangigupta3999@gmail.com

ABSTRACT: Background: Hepatitis C virus (HCV) infection remains a significant public health challenge, potentially leading to cirrhosis and hepatocellular carcinoma. Monitoring viral load and genotypes is essential for clinical management and public health planning. This study aimed to detect HCV genotypes and viral loads among infected patients in Western Uttar Pradesh.

Methods: A cross-sectional observational study was conducted from March, 2025, to April, 2026. The study included 456 patients who tested positive for HCV antibodies using a rapid diagnostic test (RDT) at Teerthanker Mahaveer Medical College and Research Centre, Teerthanker Mahaveer University, Moradabad (U.P.), 244001, India. Viral load was quantified using RT-PCR on the Quant-Studio 5 platform, and genotyping was performed using Sanger sequencing for viral-load-positive samples.

Results: Among 456 ICT-reactive records, the mean age was 45.23 ± 16.20 years (range: 6–93 years). Females accounted for 57.0% (n=260) and males for 43.0% (n=196). Most patients (92.1%) were from the inpatient department. Viral load was detected in 208 cases, with a median of 15,437.5 IU/mL (range: 52–132,972,250 IU/mL). Genotype 3a was the most common (54.8%, 114/208), followed by 1a (17.8%, 37/208). Other genotypes detected included 3b (8.7%), 1b (2.9%), and 4a (0.5%). Genotyping was not performed for 248 cases.

Conclusion: Genotype 3a is the predominant circulating HCV genotype in Western Uttar Pradesh. The high proportion of inpatient cases and the broad range of viral loads emphasize the necessity of systematic screening and genotype-guided therapy.

INTRODUCTION

Hepatitis C virus (HCV) infection is a major health problem worldwide, with an estimated 70 million people affected [1]. Chronic infection is associated with a high risk for the development of liver cirrhosis, end-stage liver disease, and hepatocellular cancer [2], [8]. The World Health Organization has set aims for the elimination of viral hepatitis as a public health issue by 2030, which calls for expanded access to diagnosis and treatment [2], [6].

In India, the epidemiology of HCV shows marked regional variation in the distribution of genotypes [5].

Unsafe medical practices and low awareness burden the highly populated area of Western Uttar Pradesh with diseases [8]. Management of HCV involves quantification of viral load to monitor infection and genotyping to assist with direct-acting antiviral (DAA) therapy [3], [5]. Its clinical importance notwithstanding, there is a lack of regional information on the molecular epidemiology of HCV in western Uttar Pradesh.

Genotype 3a has been reported to be the predominant in previous studies in North India; however, continued monitoring is required due to possible changes in the prevalence of genotypes [3], [5]. In this region, the present study was conducted to determine the genotypes and viral loads of HCV among infected patients to guide local clinical guidelines and public health strategies.

METHODS

Study Design and Setting

A cross-sectional observational study was undertaken in Teerthanker Mahaveer Medical College and Research Centre, Teerthanker Mahaveer University, Moradabad (U.P.), 244001, India, Western Uttar Pradesh. Study period: March 2025 to April 2026. The Institutional Ethical Committee gave ethical permission for a 456-sample size, and the College Research Advisory Committee (CRAC) approved the study in March 2025.

Inclusion Criteria: Patients were included if they met the following criteria:

1. The rapid diagnostic test (RDT) for HCV antibodies returned a reactive result [4].
2. Provided written informed consent for participation in the study.

Exclusion Criteria: Patients were excluded based on:

1. Current antiviral therapy for hepatitis C.
2. Completed previous treatment for HCV infection [5].

Specimen Collection and Processing

Venous blood (4 mL) was drawn from each participant and divided into two 2-mL EDTA tubes. Samples were transferred to the Molecular Laboratory, Department of Microbiology, Teerthanker Mahaveer Medical College and Research Center (TMMC and RC). Plasma was separated by centrifugation and kept in aliquots at −20°C until further testing.

Viral Load Estimation

HCV RNA viral load was assessed by RT-PCR on a Quant-Studio 5 platform (Applied Biosystems by Thermo Fisher Scientific). The procedure used the TRUPCR®-related assay RNA, which was extracted using preloaded cartridges on an automated device (Insta NX Mag 16 or similar). Results were expressed in IU/mL and log10 values. The limit of detection of the assay was [Confirm Limit of Detection, e.g., 20 or 34 IU/mL]. Samples where no RNA was found were reported as “NOT DETECTED.”

Genotyping and Subtyping

Genotyping was done on the viral-load-positive samples by the Sanger sequencing method. Samples were delivered to Redcliffe Laboratory, Noida, in sterile, triple-layer packing with frozen gel packs. Post-amplification products were evaluated on a 3500XL genetic analyzer. Sequence identification was done by comparing the results with the NCBI database using the Basic Local Alignment Search Tool (BLAST) [7]. Samples that were not sequenced were marked as “NOT PERFORMED," and those with unresolved sequences were marked as “OTHER GENOTYPES."

Statistical Analysis

The data were analyzed using [Software Name, e.g., IBM SPSS Statistics]. Continuous variables are given as mean ± standard deviation (SD) or median and range. Frequency and percentage are shown for categorical variables. For the description, viral load data were log10 transformed. The initial inputs for the sample size calculation (P=2.1%, E=1.05%, Zα/2=1.96) provided in the protocol are preliminary and are not presented here as a finished final calculation. Population prevalence was not determined, as all included subjects were HCV ICT reactive.

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RESULTS

Demographic Characteristics

A total of 456 HCV ICT-reactive patients were enrolled in the trial. The mean age of the group was 45.23 ± 16.20 years, and the median was 43.5 years (range 6-93 years). The cohort consisted of 260 (57.0%) females and 196 (43.0%) males.

Most of the patients were from the Inpatient Department (IPD) (n=420, 92.1%), whereas 36 (7.9%) were from the Outpatient Department (OPD).

Viral Load Distribution

A numeric viral load was successfully measured in 208 (45.6%) patients. The remaining 248 entries (54.4%) had a viral load result of "NOT DETECTED." The median viral load of the 208 quantified cases was 15,437.5 IU/mL, ranging from 52 to 132,972,250 IU/mL. The mean viral load was 1,224,105.56 IU/mL (mean log10: 4.2409, median log10: 4.165).

Genotype Distribution

Genotype and subtype data were available for 208 viral-load-positive records. Genotype 3a was the most frequent, being detected in 114 (54.8%) of the genotyped samples. Genotype 1a was then identified in 37 (17.8%) instances. Other genotypes were found in 32 (15.4%) cases. Subtype 3b was seen in 18 (8.7%) individuals, 1b in 6 (2.9%), and 4a in 1 (0.5%) patient (Table 2). Genotyping was "NOT PERFORMED" for 248 records. These were mostly associated with samples with undetectable virus loads.

Table 1: Demographic profile of HCV-reactive patients (n=456)

Variable	**Statistics**
Age (years)	
Mean ± SD	45.23 ± 16.20
Median	43.5
Range	6–93

Gender	**n (%)**
Female	260 (57.0%)
Male	196 (43.0%)

Settofg	**n (%)**
IPD	420 (92.1%)
OPD	36 (7.9%)

Table 2: HCV Genotype and Subtype Distribution (n=208)

Genotype/Subtype	**Frequency (n)**	**Percentage (%)**
3a	114	54.8%
1a	37	17.8%
Other Genotypes	32	15.4%

3b	18	8.7%
1b	6	2.9%
4a	1	0.5%
Total	**208**	**100.0%**

DISCUSSION

This paper presents a recent picture of HCV molecular epidemiology in Western Uttar Pradesh. Genotype 3a was predominant (54.8%), which is consistent with the findings of other portions of northern India [5], [8]. The identification of genotype 4a though rare (0.5%), is in agreement with the reports of circulating various genotypes in the Indian subcontinent [8].

The demographic profile indicates a somewhat larger percentage of females (57.0%) with mainly inpatient patients (92.1%). The wide range of viral titers, from 52 to >132 million IU/mL, illustrates the diversity in the clinical presentation of chronic HCV. Caution should be exercised in interpretation due to a significant proportion of "NOT DETECTED" viral load values (54.4%) among the antibody-reactive patients.

This may be due to spontaneous clearance of the virus, successful treatment of previous infections, or limits in the test limit of detection [1].

The main weakness of this study is the lack of genotype data for 248 patients, mostly due to undetectable virus loads. This limits our ability to draw broad inferences about the relationship between genotype and viral load across the whole antibody-reactive group. Also, the study population was restricted to patients with ICT reactivity and does not reflect the prevalence of the general community. Unresolved sequences to specific subtypes were grouped into "OTHER GENOTYPES," emphasizing the need for enhanced molecular characterization in future investigations.

CONCLUSION

Conclusion: To summarize, genotype 3a is the predominant HCV genotype among infected patients of Western Uttar Pradesh. These findings suggest the continued use of pan-genotypic DAA regimens or genotype-specific treatment when warranted. Enhanced screening and early diagnosis of viral load are crucial to reduce the burden of HCV-related liver disease in the region.

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Conflicts of Interest

"There are no conflicts of interest."

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