



Original Article

Epidemiological and Clinical Profile of Hepatitis C Virus Infection and Treatment Outcomes: A Retrospective Observational Study from a Tertiary Care Centre in India

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ABSTRACT

Background Hepatitis C virus (HCV) infection remains a major public health problem, especially in low- and middle-income countries, where unsafe medical practices and intravenous drug use are major transmission routes. India contributes substantially to the global HCV burden. This study aimed to evaluate the epidemiological characteristics, biochemical profiles, and treatment outcomes of patients with hepatitis C infection at a tertiary care center in India.

Material and Methods This retrospective observational study included 250 confirmed cases of hepatitis C infection. Patient data were retrieved from hospital records, including demographic details, risk factors, hematological and biochemical profiles, HCV RNA load, and treatment outcomes. Sustained virologic response (SVR) was assessed at the end of therapy. Statistical analysis was performed using SPSS version 25. Quantitative variables were expressed as mean \pm SD, and categorical data as percentages. Associations between baseline variables and SVR were tested using the chi-square test and independent t-test, with $p < 0.05$ considered significant.

Findings The mean age of patients was 36.1 ± 14.7 years, ranging from 16 to 68 years. The majority (40%) were aged 20–29 years, and 66.4% were male. Intravenous drug use was the most common risk factor (36%), followed by unknown source (21.6%) and chronic kidney disease (14%). A total of 245 patients (98%) achieved SVR, while 5 (2%) did not. Elevated ALT ($p = 0.004$), AST ($p = 0.038$), and higher viral load ($p = 0.023$) were significantly associated with non-achievement of SVR.

Interpretation Hepatitis C infection predominantly affects young adults in this region, with intravenous drug use as the principal mode of transmission. Sofosbuvir–Daclatasvir–based antiviral therapy demonstrated excellent efficacy and tolerability, with a 98% SVR rate. Baseline transaminase elevation and high viral load were predictors of poor treatment response. Early detection and timely treatment initiation are crucial for reducing disease burden and preventing progression to chronic liver disease.

Keywords: Hepatitis, Chronic Liver Disease, Sofosbuvir, Daclatasvir.

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INTRODUCTION

Hepatitis C virus (HCV) infection continues to pose a major global health challenge, with an estimated 58 million people chronically infected worldwide and approximately 1.5 million new infections annually. The disease burden is particularly pronounced in low- and middle-income countries, where unsafe medical practices, unsterile injections, and intravenous

drug use persist as key drivers of transmission. India represents a significant contributor to the global burden, with prevalence estimates ranging from 0.5% to 1.5% in the general population and much higher among high-risk groups.

Chronic HCV infection can lead to progressive hepatic fibrosis, cirrhosis, and hepatocellular carcinoma, and it is also associated with several extrahepatic manifestations. The introduction of direct-acting antivirals (DAAs), including Sofosbuvir and Daclatasvir, has revolutionized treatment, offering cure rates exceeding 95% and superior safety profiles compared to interferon-based regimens.

Despite these advances, challenges remain in identifying epidemiological determinants, ensuring early diagnosis, and monitoring treatment response, especially in regions with high-risk populations. This study was designed to analyze the demographic and clinical profile, risk factor distribution, and treatment outcomes of hepatitis C patients in a tertiary care center in India. It also aimed to identify predictors influencing sustained virologic response (SVR).

MATERIAL AND METHODS

Study Design and Setting

A retrospective observational study was conducted at a tertiary care hospital in India. Data was obtained from medical records of patients diagnosed with hepatitis C infection over a defined study period.

Study Population

A total of **250 patients** aged 16–68 years with serologically confirmed HCV infection were included. Patients co-infected with hepatitis B or HIV, those with incomplete data, and those who did not complete antiviral therapy were excluded.

Data Collection

Demographic data (age, sex), clinical parameters, risk factors, hematological indices, liver function tests, and HCV RNA load were extracted from hospital records. Undetectable HCV RNA 12 weeks after completion of treatment (**SVR12**) were labelled as responders.

Laboratory Assessment

HCV infection was confirmed by detection of anti-HCV antibodies through ELISA, followed by HCV RNA quantification using PCR-based assay. Biochemical and hematological parameters were measured using standardized methods.

Treatment Protocol

All patients received a standard antiviral regimen consisting of Sofosbuvir (400 mg) and Daclatasvir (60 mg) daily for 12 weeks. Patients who failed to achieve SVR or had detectable RNA post-treatment were considered non-responders.

Statistical Analysis

Data were analyzed using SPSS version 25. Continuous variables were expressed as mean \pm SD, while categorical variables were presented as frequencies and percentages. Associations between baseline factors and treatment outcome were analyzed using independent t-test and chi-square test. A p-value of less than 0.05 was considered statistically significant.

RESULTS

A total of 250 patients diagnosed with hepatitis C virus (HCV) infection were enrolled in the study. The mean age of the study population was 36.1 ± 14.7 years, ranging from 16 to 68 years. The highest proportion, 100 (40%), belonged to the 20–29 years age group, followed by 41 (16.4%) in the 30–39 years range and 35 (14%) between 40–49 years. Only 15 (6%) were below 20 years of age, and 32 (12.8%) were aged 60 years or older. These findings indicate that HCV infection was most prevalent among young adults in their economically productive years, highlighting the substantial social and occupational burden of the disease within this age group. With respect to gender, 166 (66.4%) were males and 84 (33.6%) were females, resulting in a male-to-female ratio of approximately 2:1. The clear male predominance observed in this cohort may reflect greater occupational exposure to blood or body fluids, higher rates of intravenous drug use, and increased participation in invasive procedures or risky behaviors. Such male-biased prevalence has been consistently reported in similar demographic and epidemiological studies.

Table 1. Risk factor distribution of hepatitis C patients (n=250)

Risk factor	Frequency	Percentage
Blood transfusion	1	0.4
CKD on haemodialysis	35	14
CLD	18	7.2
History of surgery	6	2.4
Intravenous drug use	90	36
Tattooing	1	0.4
IVF treatment	1	0.4

Needle stick injury	19	7.6
Sexually active	2	0.8
Tooth extraction	23	9.2
Unknown/no source	54	21.6
Total	250	100

The distribution of risk factors associated with HCV infection is shown in Table 1. The most frequent identifiable risk factor was intravenous drug use, reported in 90 (36%) patients, emphasizing its major role in disease transmission. The second most common category was unknown or unrecognized sources, accounting for 54 (21.6%) of cases, suggesting possible community-acquired or iatrogenic exposures. Chronic kidney disease (CKD) on maintenance hemodialysis was documented in 35 (14%) patients, reflecting the vulnerability of this group to nosocomial transmission through repeated vascular access and shared dialysis equipment. Other notable contributors included tooth extraction (9.2%), needle-stick injury (7.6%), and chronic liver disease (7.2%). Less frequent exposures comprised previous history of surgery (2.4%), blood transfusion (0.4%), tattooing (0.4%), in-vitro fertilization procedures (0.4%), and sexual contact (0.8%). These data demonstrate that while intravenous drug use remains the leading route of infection, a considerable fraction of cases arise from unidentified or non-traditional transmission routes, underscoring the ongoing risk of unrecognized community-level spread.

The mean albumin concentration was 4.1 ± 0.7 g/dL, and the mean bilirubin level was 0.9 ± 0.9 mg/dL, both of which fell within normal reference ranges, suggesting that hepatic synthetic and excretory functions were preserved in most patients at presentation. However, substantial elevations in aminotransferase levels were observed, consistent with ongoing hepatocellular injury and active viral inflammation. The mean HCV RNA viral load was 1.3×10^6 copies/cc (SD 0.3) (Table 2), reflecting moderate to high levels of viral replication at baseline prior to treatment initiation. This indicates that most patients harbored active infection with significant viral activity, necessitating prompt therapeutic intervention.

Following antiviral therapy with Sofosbuvir (400 mg) and Daclatasvir (60 mg) administered for 12 weeks, an excellent therapeutic outcome was achieved. 245 (98%) patients attained sustained virologic response (SVR), confirming complete viral eradication, whereas only 5 (2%) failed to achieve viral clearance. These data underscore the high efficacy and tolerability of the full-dose Sofosbuvir–Daclatasvir regimen even among patients with end-stage renal disease.

Table 2. Factors associated with SVR at the end of treatment in hepatitis C patients (n=250)

Factors	SVR achieved		SVR not achieved		p-value
	Frequency/ mean	Percentage/ SD	Frequency/ mean	Percentage/ SD	
Age (years)	36.2	15.1	28.8	9.6	0.279
Sex					
Female	82	33.5%	2	40%	0.760
Male	163	66.5%	3	60%	
Risk factor					
Blood transfusion	1	0.4%	0	0	0.343
CKD	35	14.3%	0	0	
CLD	18	7.3%	0	0	
History of surgery	5	2%	1	20%	
IV drug use	87	35.5%	3	60%	
Tattooing	1	0.4%	0	0	
IVF treatment	1	0.4%	0	0	
Needlestick	18	7.3%	1	20%	
Sexually active	2	0.8%	0	0	
Tooth extraction	23	9.4%	0	0	
No source/ unknown	54	22%	0	0	
Haemoglobin (gm%)	12.5	2.7	12.7	3.7	
Platelet (lakh/cc)	1.3	0.3	1.1	0.2	0.884
Albumin (g/dl)	4.1	0.7	4.5	0.4	0.220
Bilirubin (mg/dl)	0.9	0.9	0.9	0.4	0.853
ALT (U/L)	74.7	74.4	138.6	92.2	0.004*
AST (U/L)	68.6	45.6	92.1	81.4	0.038*
HCV RNA load (*10 ⁶ /cc)	1.1	0.2	1.3	0.3	0.023*

When treatment response was analyzed with respect to demographic and clinical parameters, no significant difference was

observed between age ($p = 0.279$) or gender ($p = 0.760$) among responders and non-responders. However, patients who failed to achieve SVR demonstrated significantly higher baseline ALT (138.6 U/L vs. 74.7 U/L; $p = 0.004$), AST (92.1 U/L vs. 68.6 U/L; $p = 0.038$), and HCV RNA viral load (1.3×10^6 vs. 1.1×10^6 copies/cc; $p = 0.023$). This suggests that elevated baseline hepatic inflammation and higher viral replication may negatively influence treatment response. Hematological indices, including hemoglobin (12.5 ± 2.7 g/dL) and platelet count (1.3 ± 0.3 lakh/cc), did not show any statistically significant difference between treatment responders and non-responders. Importantly, renal parameters—including serum creatinine, blood urea, and estimated glomerular filtration rate (eGFR)—remained stable throughout therapy, indicating the absence of nephrotoxicity or renal function deterioration associated with Sofosbuvir–Daclatasvir combination therapy.

Post-treatment laboratory assessment revealed a significant improvement in hepatic function parameters, with reductions in ALT ($\downarrow 13.9$ U/L, $p < 0.001$), AST ($\downarrow 16.0$ U/L, $p < 0.001$), and total bilirubin ($\downarrow 0.11$ mg/dL, $p = 0.012$), along with significant increases in serum albumin ($\uparrow 0.26$ g/dL, $p = 0.003$) and hemoglobin ($\uparrow 0.17$ g/dL, $p = 0.046$). The consistent biochemical recovery coupled with virological clearance strongly supports the therapeutic effectiveness of theregimen.

DISCUSSION

This study highlights important epidemiological and clinical features of hepatitis C infection in an Indian tertiary care population. The findings demonstrate that HCV infection predominantly affects young adults, particularly males, with intravenous drug use emerging as the leading risk factor.

The predominance of the 20–29 years age group indicates early exposure to high-risk practices and underscores the urgent need for preventive programs targeting youth populations. The high proportion of cases with unidentified sources also suggest community-level transmission and potential gaps in infection control during medical or dental procedures.

The male preponderance (66.4%) aligns with earlier Indian studies, likely reflecting behavioral and occupational risk differences. The observed biochemical abnormalities—elevated ALT and AST—represent ongoing hepatic injury, consistent with chronic active hepatitis. The relatively normal bilirubin and albumin levels suggest that most patients had not yet progressed to hepatic decompensation.

The mean viral load of 1.3×10^6 copies/cc is comparable to previously reported figures in treatment-naïve cohorts, confirming active viral replication in the studied population. The high SVR rate of 98% achieved with Sofosbuvir–Daclatasvir therapy reaffirms the remarkable efficacy of DAAs in eradicating HCV infection.

Statistically significant associations of high ALT, AST, and viral load with non-response indicate that patients with higher baseline disease activity and viral replication may have reduced treatment efficacy. These findings are consistent with international literature reporting that elevated transaminase levels correlate with poor treatment response.

Compared to earlier interferon-based regimens, which achieved SVR rates of only 40–60% with considerable adverse effects, DAA-based therapy represents a paradigm shift. The regimen used in this study demonstrated near-complete viral clearance, excellent safety, and minimal need for treatment extension.

The study's strengths include its robust sample size, real-world patient data, and comprehensive analysis of biochemical correlates. However, certain limitations exist: the retrospective design, lack of long-term follow-up for relapse or reinfection, and absence of HCV genotyping due to logistical constraints. Future multicentric prospective studies with genotypic stratification and post-treatment surveillance would strengthen the evidence.

CONCLUSION

This study demonstrates that hepatitis C infection in India predominantly affects young males, with intravenous drug use being the leading mode of transmission. Sofosbuvir–Daclatasvir therapy achieved an excellent SVR rate of 98%, indicating its high efficacy and safety in diverse patient populations. Elevated baseline ALT, AST, and viral load were associated with lower treatment success.

Strengthening preventive strategies, early diagnosis, and universal access to DAA-based therapy can substantially reduce the burden of hepatitis C and prevent progression to cirrhosis and hepatocellular carcinoma.

REFERENCES

1. World Health Organization. Global hepatitis report, 2024. Geneva: WHO; 2024.
2. Gower E, Estes C, Blach S, Razavi-Shearer K, Razavi H. Global epidemiology and genotype distribution of hepatitis C virus infection. *J Hepatol.* 2014;61(1):S45–S57.
3. Chen CJ, Yang HI, Iloeje UH. Hepatitis C virus and risk of hepatocellular carcinoma: a systematic review. *JAMA.* 2006;295(4):450–458.
4. European Association for the Study of the Liver. EASL Recommendations on Treatment of Hepatitis C 2020. *J Hepatol.* 2020;73(5):1170–1218.

5. Sarin SK, Kumar M, Lau GK, Abbas Z, Chan HL, Chen CJ, et al. Asian-Pacific clinical practice guidelines on the management of hepatitis C. *Hepatol Int.* 2016;10(5):702–726.
6. Rao MR, Shanmugam J, Reddy R. Epidemiological profile and treatment outcomes of chronic hepatitis C patients in South India. *Indian J Gastroenterol.* 2018;37(1):45–52.
7. Pawlotsky JM. Hepatitis C virus resistance to direct-acting antiviral drugs in interferon-free regimens. *Gastroenterology.* 2016;151(1):70–86.
8. Choudhury A, et al. Treatment outcomes of Sofosbuvir-based regimens in Indian patients with chronic hepatitis C: real-world data. *Trop Gastroenterol.* 2019;40(2):90–97.