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Original Article

Clinical Profile of Newly diagnosed Hepatitis C positive patients with special reference to treatment response with DAA (Direct Antiviral Agents)

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ABSTRACT

Hepatitis C virus (HCV) infection is a major cause of chronic liver disease worldwide and continues to contribute substantially to global morbidity and mortality. The advent of direct-acting antivirals (DAAs) has revolutionized the therapeutic landscape, offering high cure rates, improved tolerability, and short treatment duration compared to interferon-based therapies. This prospective observational study evaluated the clinical profile and treatment outcomes of 50 newly diagnosed hepatitis C patients attending the Department of Medicine, JMCH. The majority of patients were young males and asymptomatic at diagnosis, with intravenous drug use being the predominant risk factor for infection. All patients received a 12-week DAA regimen and were evaluated for sustained virological response (SVR) 12 weeks post-therapy. SVR was achieved in 49 patients (98%), demonstrating excellent real-world efficacy of DAAs in this cohort. The findings highlight the critical importance of early screening and targeted intervention among high-risk populations to prevent progression to chronic liver disease.

Keywords*: Hepatitis C Virus; Direct-Acting Antivirals; Sustained Virological Response*

INTRODUCTION

Hepatitis C virus (HCV) infection remains a significant public health concern globally and a major cause of chronic liver disease, cirrhosis, hepatocellular carcinoma, and liver-related mortality. Approximately 58 million individuals are estimated to be chronically infected with HCV worldwide, with nearly 1.5 million new infections recorded annually. The infection is characteristically asymptomatic in its early stages and frequently remains undiagnosed until the development of advanced hepatic complications. This silent natural history contributes to delayed treatment initiation and poor disease outcomes in many cases.

The epidemiology of HCV varies by region and risk profile. In India, HCV prevalence ranges from 0.5 % to 1.5 %, with considerable variation in certain subpopulations. The northeastern region of India has witnessed a disproportionately higher burden of HCV, especially among intravenous drug users (IVDUs), where needle-sharing practices represent a major route of transmission. This shifting epidemiology—from transfusion-linked transmission to behavioural exposure—emphasizes the evolving public health challenge in the country. Routine screening of high-risk groups and early diagnosis are critical to mitigating long-term complications.

The introduction of direct-acting antivirals (DAAs) marked a paradigm shift in HCV management. DAAs inhibit viral replication through targeted blockade of essential viral proteins, producing rapid viral load suppression with cure rates exceeding 95% in most patient subgroups. Their favourable tolerability profile, minimal adverse events, and oral once-daily dosing have significantly improved therapeutic adherence. The World Health Organization now aims to eliminate HCV as a public health threat by 2030, advocating for the expansion of DAA-based treatment access in high-prevalence regions.

Despite their success, real-world outcomes may be influenced by demographic, behavioural and socioeconomic factors. Regions with heavy substance-use burden face additional challenges including stigma, risk of reinfection, financial limitations, and poor awareness regarding hepatitis. Understanding real-world treatment outcomes and clinical characteristics of newly diagnosed patients in such populations is essential for effective disease elimination strategies.

With this background, the present study was conducted to assess the clinical profile and treatment response to DAA-based therapy among newly diagnosed hepatitis C patients at a tertiary care teaching hospital. The findings provide insight into the regional epidemiological pattern and real-world therapeutic effectiveness, which may guide clinical practice and public health policy.

MATERIALS AND METHODS

This hospital-based prospective observational study was conducted in the Department of Medicine, Jorhat Medical College & Hospital (JMCH), Assam, over 12 months. A total of 50 newly diagnosed hepatitis C patients attending the outpatient department and medical wards during the study period were consecutively enrolled. Diagnosis of HCV infection was established using third-generation ELISA for anti-HCV antibodies followed by quantitative HCV RNA measurement using real-time polymerase chain reaction (RT-PCR). Patients with a history of prior antiviral therapy for HCV, established chronic liver disease of other etiologies, or unwillingness to undergo treatment were excluded. Patients below 12 years of age or with HIV and Hep B coinfections were excluded.

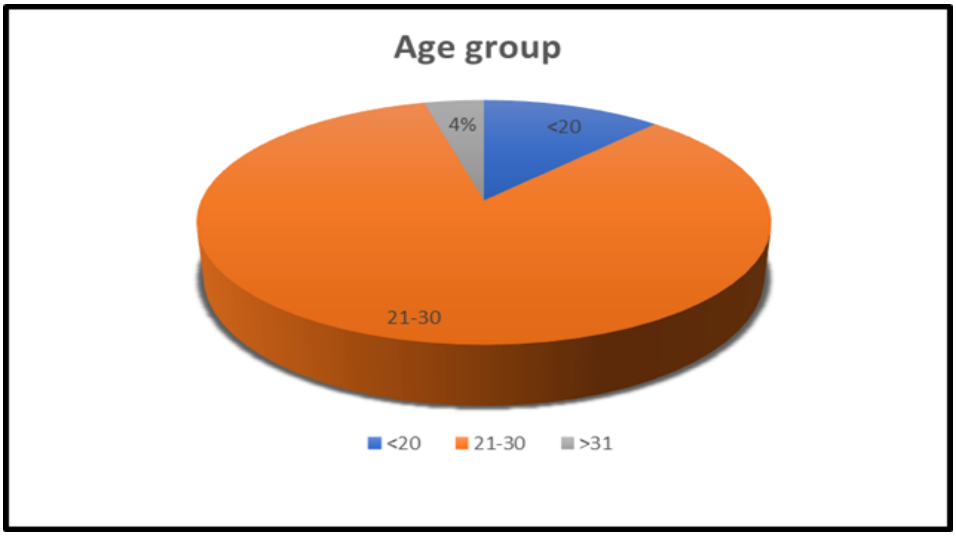
All participants underwent a comprehensive clinical evaluation including demographic details, symptoms at presentation, risk factor assessment, comorbid illnesses, and relevant medical or surgical history. Laboratory investigations included complete blood count, liver and renal function tests, coagulation profile, fasting blood glucose and viral marker screening for hepatitis B and HIV. Liver fibrosis assessment was performed using the AST-to-Platelet Ratio Index (APRI score). Ultrasonography (USG) of the abdomen was conducted to assess the liver parenchymal pattern and identify radiological abnormalities such as splenomegaly or ascites.

All patients were initiated on DAA therapy as per prevailing guidelines, predominantly the sofosbuvir-daclatasvir combination for 12 weeks. Treatment adherence and tolerability were monitored throughout the therapy. Sustained virological response (SVR), defined as undetectable HCV RNA 12 weeks after completion of therapy, was considered treatment success. Data were recorded in a structured proforma and compiled in Microsoft Excel. Quantitative variables were expressed as mean ± standard deviation, and categorical variables as frequency and percentage. Ethical clearance was obtained from the Institutional Ethics Committee, and written informed consent was obtained from all participants.

RESULTS

Age Distribution

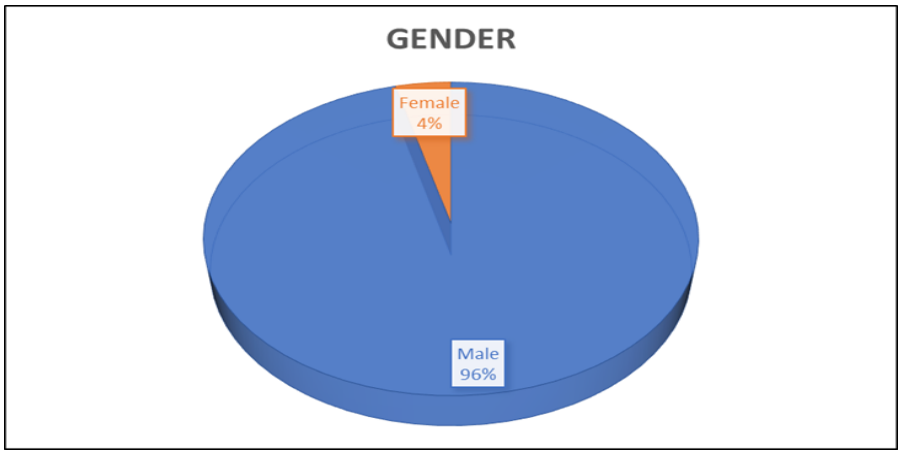
Age group (years)	Number of Patients (n)	Percentage (%)
<20	6	12.0
21–30	42	84.0
>31	2	4.0
Total	50	100.0



The mean age of the 50 study participants was 31.8 ± 8.6 years, with the highest representation in the 21–30-year age group.

Gender Distribution

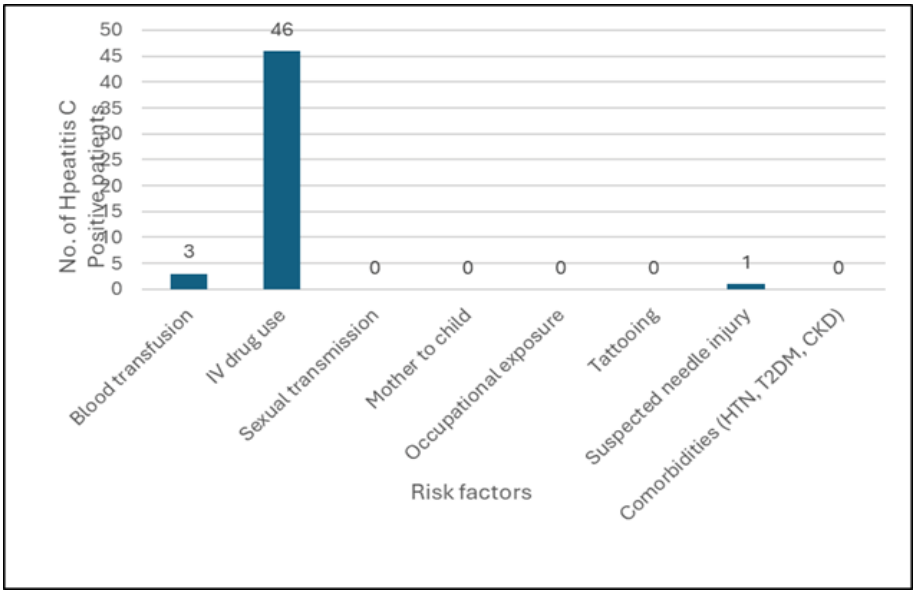
Gender	Number of Patients (n)	Percentage (%)
Male	**48**	**96.0**
Female	**2**	**4.0**
Total	**50**	**100.0**



There was a striking predominance of males (96%), reflecting gender-linked behavioural differences in risk exposure.

Risk Factors

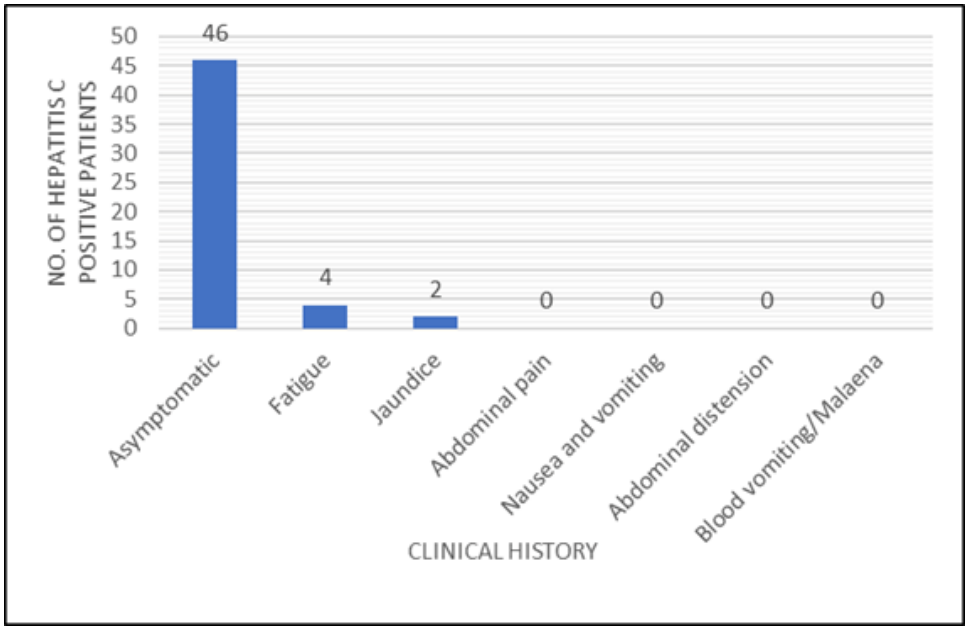
Risk factor	Patients(n)	Percentage (%)
Blood transfusion	3	6.0
IV drug use	46	92.0
Sexual transmission	0	0
Mother to child	0	0
Occupational exposure	0	0
Tattooing	0	0
Suspected needle injury	1	2
Comorbidities (HTN, T2DM, CKD)	0	0
Total	50	100%



Intravenous drug use was the most common risk factor, reported by 92% of participants, underscoring the strong association between substance-use practices and HCV transmission in the region. A smaller number reported multiple blood transfusions or needle-stick injury as the probable mode of acquisition. Diabetes mellitus was the most frequent comorbidity, while the majority had no significant medical illness.

Clinical History

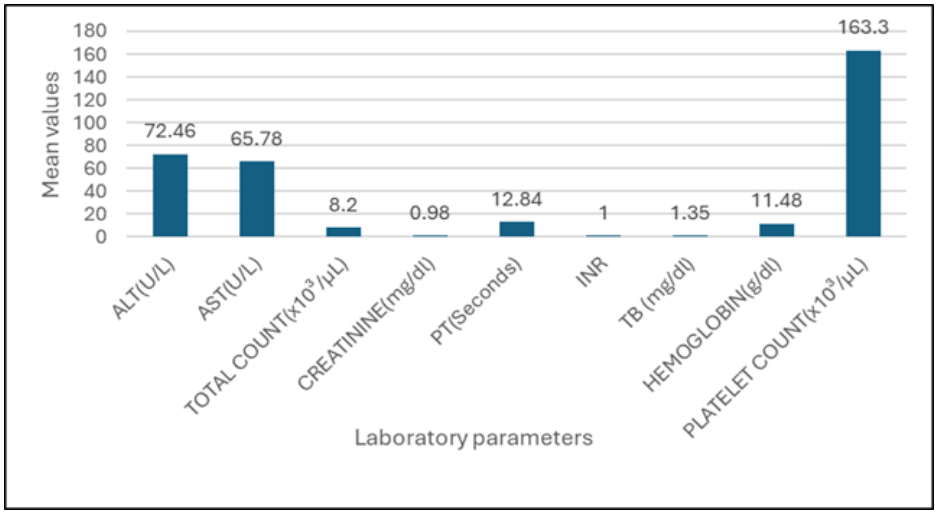
Clinical history	Number of patients(n)	Percentage (%)
Asymptomatic	46	92%
Fatigue	4	8%
Jaundice	2	4%
Abdominal pain	0	0
Nausea and vomiting	0	0
Abdominal distension	0	0
Blood vomiting/Malaena	0	0



Nearly all participants (92%) were asymptomatic at presentation, with most diagnoses made during routine screening or evaluation for unrelated health issues.

Pre- and Post-Treatment Laboratory Parameters

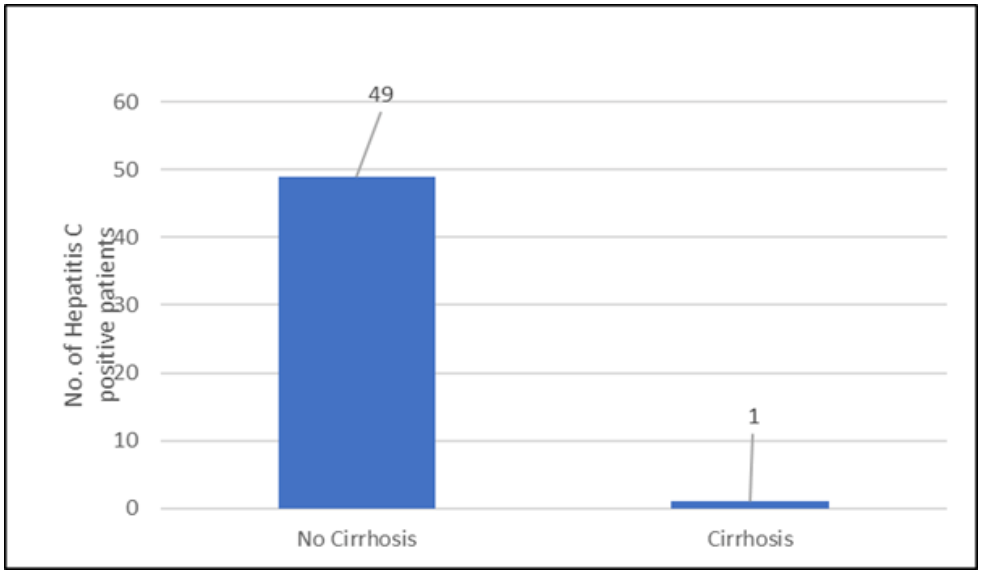
Parameters	Pre-Treatment (Mean ± SD)	Post-Treatment (Mean ± SD)	Reference Range
ALT (U/L)	72.46 ± 38.02	28.6 ± 6.4	**7–56**
AST (U/L)	65.78 ± 27.72	26.9 ± 5.8	**10–40**
Total Count (×10³/µL)	8.2 ± 1.61	7.4 ± 1.2	**4.0–11.0**
Creatinine (mg/dL)	0.98 ± 0.15	0.92 ± 0.14	**0.6–1.2**
PT (seconds)	12.84 ± 1.51	12.1 ± 0.9	**11–15**
INR	1.00 ± 0.09	1.01 ± 0.06	**0.9–1.1**
Total Bilirubin (mg/dL)	1.35 ± 0.58	0.78 ± 0.21	**0.2–1.2**
Hemoglobin (g/dL)	11.48 ± 1.47	13.9 ± 1.3	**13–17**
Platelet Count (×10³/µL)	163.3 ± 68.42	232.5 ± 52.6	**150–450**



There was increase in AST,ALT in the patients suggestive of chronic hepatic inflammation which resolved post treatment with DAA.

APRI Score Distribution

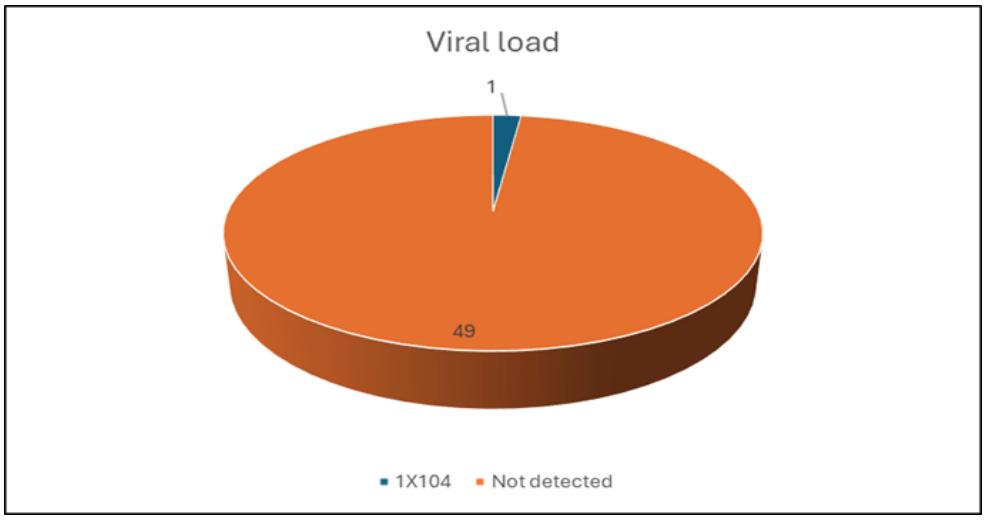
Cirrhosis	Frequency (n)	Percentage (%)
No cirrhosis (<2)	49	98.0
Cirrhosis (>2)	1	2.0
Total	50	100.0



APRI scoring revealed minimal hepatic fibrosis in most patients, although a minority exhibited moderate-to-advanced fibrosis

Viral load, 3 months post treatment (SUSTAINED VIROLOGICAL RESPONSE)

Pre treatment viral load. (IU/ml)	Post treatment viral load. (IU/ml)	Frequency(n)	Percentage(%)	p value
Detected	$1X10^4$	1	2.0	
Detected	Not detected	49	98.0	
		50	100.0	<0.005



All patients completed a full 12-week regimen of direct-acting antivirals, predominantly sofosbuvir plus daclatasvir. Treatment adherence was excellent and no major adverse drug reactions were reported. At 12 weeks post-treatment, sustained virological response was achieved in 49 out of 50 patients (98%), indicating highly successful viral clearance after DAA therapy. One patient failed to respond and was classified as a non-responder.

DISCUSSION

The present study highlights key epidemiological and therapeutic characteristics of hepatitis C in a high-risk population from Northeast India. The predominance of young males, behavioural exposure through intravenous drug use, asymptomatic presentation and excellent response to DAA therapy mirror the changing landscape of HCV in India and globally. 21-30 is the most commonly reported age group for Hepatitis-C (**Smith J, Brown P, Taylor D., 2021; Patel, S., Kumar, R., & Das, A., 2020**). the findings of this study was consistent with **Roberts et al. (2021).** who also found that men are more likely to be diagnosed with incidental screaming as they are mostly engaged with high risk behavior like Injectable drug and occupational exposure. In another study by **Patel, R., & Kumar, S (2020)** also found similar results where male were screened with incidental screening due to their major representation in high-risk occupation. Historically, transmission of HCV was largely associated with unsafe transfusion practices; however, improved blood banking systems have reduced transfusion-linked HCV substantially. In contrast, the increasing prevalence among individuals with substance-use disorders has emerged as an important public health challenge.

The predominance of asymptomatic cases in the present study aligns with the natural history of HCV, where subclinical infection persists for years before progressing to cirrhosis or hepatocellular carcinoma. Early detection in high-risk groups is therefore of paramount importance. The young age profile also indicates a pressing need to integrate hepatitis screening with substance-use rehabilitation programmes, educational outreach and targeted public health strategies. **Carter, L., Johnson, T., & Roberts, M. (2021)** in his study essentially found that a big share of Hepatitis C cases were recognized through schedule screening, especially in high-risk age bunches. A large-scale epidemiological think about by **Lee, J., Kim, H., & Park, S (2019)** too recognized youthful adults (21-30 years) as the foremost influenced gather, strengthening the design watched in this investigate.

The virological cure rate (SVR = 98%) observed in this study is consistent with outcomes reported in large clinical trials and real-world studies evaluating sofosbuvir-daclatasvir regimens. The near-universal adherence and absence of significant adverse drug reactions reflect the high tolerability of DAAs and the ease of once-daily oral therapy. These findings reinforce the superior therapeutic performance of DAAs compared to interferon-based regimens, which were previously associated with poor tolerance and variable cure rates. A large-scale epidemiological think about by **Lee, J., Kim, H., & Park, S (2019)** too recognized youthful adults (21-30 years) as the foremost influenced gather, strengthening the design watched in this investigate. This study shows that direct-acting antivirals (DAAs) are a very efficient treatment for hepatitis C in both men and women, with a 98% cure rate (undetectable viral burden after treatment). study by **Miller, T., Scott, H., & Davidson, K. (2019)**

However, the potential risk of reinfection among individuals who continue intravenous drug use remains a key challenge. Although this study did not include long-term follow-up post-SVR, published literature suggests that reinfection risk may be substantial in high-risk groups without behavioural counselling and harm-reduction services. Consequently, antiviral therapy must be integrated with preventive interventions such as opioid substitution programs, safe needle initiatives, mental-health support and community engagement.

Overall, this study demonstrates that highly effective HCV care is achievable even in vulnerable groups when DAAs are made accessible. However, sustainable progress toward HCV elimination requires strengthening screening programs, addressing stigma, improving public awareness, and integrating substance-use rehabilitation with hepatitis care.

CONCLUSION

Direct-acting antivirals are highly effective in achieving sustained virological clearance in newly diagnosed hepatitis C patients which is also evident from previously established studies worldwide. Early screening of high-risk populations, timely initiation of antiviral therapy and integration of social awareness are essential for long-term HCV control and prevention of disease progression.

LIMITATIONS

This study was limited by its single-centre design and modest sample size. Genotyping and long-term post-cure monitoring to evaluate reinfection risk were not feasible due to resource constraints. Larger multicentric studies with long-term follow-up are warranted.

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