IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 24, Issue 6 Ser. 4 (June. 2025), PP 05-11
www.iosrjournals.org

A Study Of Epidemiology, Clinical, Laboratory Profile, And Treatment Profile Of Patients With Hepatitis C

Dr Mani Srikanth Manam, Dr. Meyyammai Chidambaram,
Dr. Srinivasagalu Krishnasamy
Postgraduate[1], Assistant Professor[2], Professor [3]*
Department Of General Medicine
Meenakshi Medical College Hospital & Research Institute
Meenakshi Academy Of Higher Education & Research (Deemed To Be University), Kanchipuram, Tamil Nadu, India

Abstract
Introduction:
Hepatitis C virus (HCV) is a major contributor to chronic liver disease(CLD), cirrhosis, and hepatocellular carcinoma(HCC). It affects over 58 million people globally. In spite of availability of highly effective direct-acting antivirals (DAAs), data on the clinical and treatment profiles of HCV-infected individuals in India remain limited. This study was done to asssess epidemiological, clinical, laboratory, and therapeutic characteristics of HCV patients at a medical college in South India.
Materials & Methods:
This pcross-sectional observational study was done at Meenakshi Medical College Hospital and Research Institute between November 2023 and April 2024. Fifty treatment-naïve patients aged 18–45 years with confirmed HCV infection were enrolled. Baseline demographics, clinical symptoms, laboratory parameters (CBC, LFTs, renal function, HCV RNA), and ultrasound abdomen findings were recorded. All patients received DAAs as per national guidelines and were followed up for 12 weeks to assess Sustained Virologic Response (SVR12). Data were analyzed using Epi Info version 7.2.5.0.
Results:
Most patients were aged 26–35 years (50%) and. 64% were male. Fatigue (70%) was the most common symptom, and 30% were asymptomatic. Elevated liver enzymes (ALT: 82.4 ± 35.2 U/L, AST: 76.1 ± 32.8 U/L) were observed, and 20% showed early cirrhotic changes on ultrasound. Most patients (90%) received Sofosbuvir + Velpatasvir. At 12 weeks, 96% achieved SVR12.
Conclusion:
HCV infection mainly affects young adults and is asymptomatic. Prompt diagnosis and treatment with DAAs can produce excellent clinical outcomes. Enhancing screening and treatment access is essential for achieving HCV elimination goals.

Keywords: *Hepatitis C, HCV, Direct-Acting Antivirals, Epidemiology, SVR12, South India, Tertiary Care Study*

Date of Submission: 01-06-2025 Date of Acceptance: 10-06-2025

I. Introduction

Hepatitis C virus (HCV) infection is a major cause of CLD, affecting around 58 million people globally, with 1.5 million new infections annually [1]. The disease burden of HCV has steadily increased over the past few decades, primarily due to the asymptomatic nature of early infection, the risk of chronic progression, and underdiagnosis in the general population. Hepatitis C is an RNA virus of *Flaviviridae* family and is characterized by high genetic variability, with six major genotypes and multiple subtypes. This genetic diversity has main role in disease progression, treatment response, and epidemiological distribution [2].

Transmission of HCV is predominantly through parenteral exposure to infected blood. Key risk factors include unsafe injection practices, transfusion of unscreened blood or blood products, hemodialysis, needle-stick injuries, intravenous drug use (IVDU), and less commonly, through sexual contact or vertical transmission from mother to child [3]. In India, the seroprevalence of HCV infection shows considerable variation across different regions and risk groups, ranging from 0.09% in voluntary blood donors to as high as 15% in high-risk populations such as people who inject drugs (PWID) and those with multiple blood transfusions [4].

The clinical spectrum of HCV infection varies widely. While many patients remain asymptomatic for years, a subset progresses to chronic hepatitis, leading to liver fibrosis, cirrhosis, hepatic decompensation, and

hepatocellular carcinoma (HCC). Clinical manifestations, when present, are often non-specific, including fatigue, malaise, anorexia, jaundice, or signs of advanced liver disease such as ascites or encephalopathy. The natural history of HCV infection is influenced by host factors (age, gender, alcohol intake, co-infection with HBV/HIV), viral factors (genotype, viral load), and treatment access [5].

Laboratory evaluation plays a crucial role in diagnosing and monitoring HCV. Initial screening is done using anti-HCV antibody tests, followed by HCV RNA PCR for confirmation. Liver function tests (LFTs), complete blood count (CBC), coagulation profile, and non-invasive fibrosis assessments like APRI and FIB-4 scores are routinely used to assess the extent of hepatic involvement. Genotyping helps in guiding treatment decisions, though its relevance has decreased in the era of pangenotypic direct-acting antivirals (DAAs) [6].

Treatment landscape for HCV has evolved with development of DAAs, which provide sustained virologic response (SVR) rates of over 95%, minimal side effects, and shorter treatment durations. These agents have replaced older pegylated interferon and ribavirin regimens that were associated with poor tolerability and lower cure rates. India's National Viral Hepatitis Control Program (NVHCP), launched in 2018, helps in eliminating viral hepatitis as a public health threat by 2030 through free diagnosis and DAA-based treatment under the National Health Mission [7].

In spite of effective treatment presence, real-world data from tertiary care centers regarding the demographic, clinical, laboratory, and treatment profile of HCV-infected patients is limited in many parts of India. Understanding these parameters is needed to improve early diagnosis, optimize treatment strategies, and enhancing public health programs.

This prospective, observational study was done at a medical college to evaluate the epidemiological profile, clinical presentation, laboratory parameters, and treatment outcomes among patients diagnosed with hepatitis C. The findings are expected to provide insights into the disease burden, patient characteristics, and therapeutic response patterns in a real-world Indian healthcare setting.

II. Materials & Methods

Study Design and Setting

This was a cross-sectional observational study. The study was done at Meenakshi Medical College Hospital and Research Institute, a tertiary care center in Kanchipuram, Tamil Nadu, South India. The study was carried for 6 months, from November 2023 to April 2024.

Study Population

Patients diagnosed with HCV infection attending the outpatient departments (General Medicine, Medical Gastroenterology), emergency services, and those admitted to wards or ICU were screened for eligibility.

Inclusion Criteria

- Age between 18 and 45 years
- Confirmed diagnosis of HCV infection, based on positive Anti-HCV antibody or HCV RNA testing
- No prior treatment for hepatitis C (treatment-naïve)
- Good general performance status
- Willingness to provide informed written consent

Exclusion Criteria

- Co-infection with HIV or hepatitis B
- Pregnant or lactating women
- Patients with decompensated liver disease
- Presence of severe psychiatric illness
- Known contraindications to antiviral therapy

Sample Size

$N = Z^2PQ/E^2$,

where

- P = estimated prevalence of HCV = 2.5% (from previous literature)
- Q = 1 – P
- E = margin of error = 7%
- Z = value for 99% confidence interval

Minimum sample size was 31, but to account for potential dropouts, 50 patients were included.

Study Protocol

1. Screening and Consent: Eligible patients were screened using HCV antibody testing, and those testing positive were confirmed with HCV RNA (quantitative PCR).
2. Baseline Assessment:

1. Demographic and clinical history (age, sex, occupation, presenting complaints)
2. Physical examination including vital signs and general/systemic examination
3. Calculation of Body Mass Index (BMI)

3. Laboratory Investigations:

1. HCV Viral Load (Quantitative PCR) – Pre-treatment and 12 weeks post-treatment
2. Liver Function Tests (LFTs) – ALT, AST, total and direct bilirubin
3. Renal Function Tests – Serum creatinine
4. Complete Blood Picture (CBP) – Hemoglobin, platelet count
5. Ultrasound Abdomen (USG) – To assess liver size, parenchymal echotexture, and presence of cirrhosis or ascites

4. Treatment Protocol:

1. Treatment was initiated according to National Guidelines for Diagnosis and Management of Viral Hepatitis (2018).
2. Patients were prescribed pangenotypic Direct-Acting Antivirals (DAAs), for 12 weeks, with or without ribavirin based on liver status and comorbidities.
3. Medication adherence and side effect profile were monitored during the treatment course.

5. Follow-up and Assessment of Treatment Response:

1. Patients were followed for 12 weeks post-initiation of therapy.
2. HCV RNA levels were rechecked at the end of therapy to assess Sustained Virologic Response (SVR12).
3. Adverse drug reactions, if any, were recorded systematically.

Data Collection Tools: A structured proforma was used to record patient details, clinical findings, investigation results, treatment regimen, side effects, and follow-up outcomes. Data entry was done in MS Excel 2021.

Statistical Analysis

Data were analyzed using Microsoft Excel and EPI INFO version 7.2.5.0. Mean and standard deviation (SD) are used for continuous variables; frequencies and percentages for used for some categorical variables.

Inferential statistics: Chi-square test for associations between categorical variables (e.g., symptoms vs. treatment outcome). Unpaired T-test for comparison of viral loads between subgroups (e.g., high vs. low baseline viral load). Paired T-test to compare pre- and post-treatment viral loads. A p-value < 0.05 was considered statistically significant.

Ethical Considerations

The study was conducted by the ethical principles outlined by ICMR. Informed consent was taken from all patients. Patient confidentiality and privacy were strictly maintained.

III. Results

Table 1: Demographic and Epidemiological Profile of Study Participants (n = 50)

Variable	Frequency (n)	Percentage (%)
Age Group (years)		
18–25	10	20.0
26–35	25	50.0
36–45	15	30.0
Gender		
Male	32	64.0
Female	18	36.0
Occupation		
Manual labourer	20	40.0
Office worker	10	20.0
Homemaker	12	24.0
Student	4	8.0
Unemployed	4	8.0
Risk Factors		

Variable	Frequency (n)	Percentage (%)
History of transfusion	12	24.0
IV drug use	8	16.0
Dental procedures	10	20.0
Unidentified	20	40.0

In this study involving 50 Hepatitis C patients, the majority were in the 26–35 age group (50%), followed by 36–45 years (30%) and 18–25 years (20%). Males constituted a larger proportion (64%) compared to females (36%). Most participants were manual laborers (40%), followed by homemakers (24%), office workers (20%), and students or unemployed individuals (8% each). Regarding risk factors, 24% had a history of blood transfusion, 20% reported prior dental procedures, 16% had a history of intravenous drug use, while in 40% of cases, the source of infection remained unidentified, reflecting the hidden burden of HCV in the community.

Table 2: Clinical Presentation of Study Participants

Symptom	Number of Patients (n)	Percentage (%)
Fatigue	35	70.0
Abdominal pain	20	40.0
Jaundice	12	24.0
Anorexia	10	20.0
Weight loss	8	16.0
No symptoms (asymptomatic)	15	30.0

Among the 50 patients studied, fatigue was the most common presenting symptom, reported by 70% of participants, followed by abdominal pain in 40%. Jaundice was observed in 24%, while anorexia and weight loss were seen in 20% and 16% of patients, respectively. Interestingly, 30% of the patients were asymptomatic, highlighting the silent nature of HCV infection in a significant portion of cases, which underscores the importance of screening in at-risk populations.

Table 3: Laboratory Profile of Study Participants

Parameter	Mean ± SD	Normal Range
Hemoglobin (g/dL)	12.3 ± 1.6	12–16
Platelet count (×10⁹/L)	185 ± 45	150–400
ALT (U/L)	82.4 ± 35.2	< 40
AST (U/L)	76.1 ± 32.8	< 40
Serum Bilirubin (mg/dL)	1.4 ± 0.7	0.3 – 1.2
Serum Creatinine (mg/dL)	0.9 ± 0.3	0.6 – 1.2
HCV RNA Baseline (IU/mL)	1,500,000 ± 750,000	Detectable = >15 IU/mL

The laboratory profile of the study participants revealed mild anemia, with a mean hemoglobin of 12.3 ± 1.6 g/dL, and a normal platelet count averaging 185 ± 45 ×10⁹/L. Liver enzymes were markedly elevated, with mean ALT and AST levels of 82.4 ± 35.2 U/L and 76.1 ± 32.8 U/L, respectively—both significantly above the normal upper limit of 40 U/L—indicating ongoing hepatic inflammation. The mean serum bilirubin was 1.4 ± 0.7 mg/dL, slightly above the normal range, suggestive of mild hepatic dysfunction. Serum creatinine remained within normal limits (0.9 ± 0.3 mg/dL), indicating preserved renal function. The baseline HCV RNA viral load was high, averaging 1,500,000 ± 750,000 IU/mL, consistent with active viral replication.

Table 4: Liver Ultrasound Findings (USG Abdomen)

Finding	Frequency (n)	Percentage (%)
Normal liver echotexture	18	36.0
Mild hepatomegaly	12	24.0
Fatty liver (Grade I/II)	10	20.0
Early cirrhotic changes	10	20.0

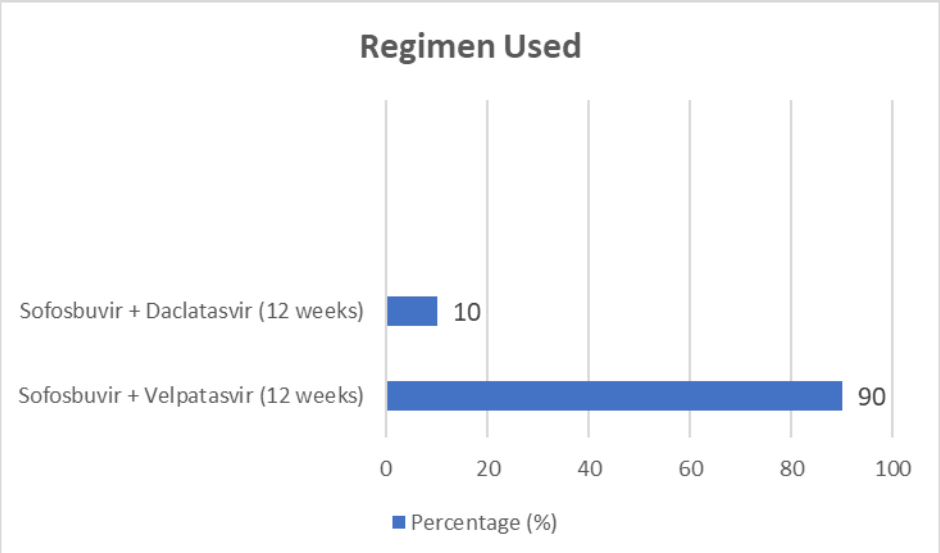
Ultrasound abdomen findings among the study participants showed that 36% had a normal liver echotexture, while 24% exhibited mild hepatomegaly, indicating early liver enlargement. Fatty liver changes (Grade

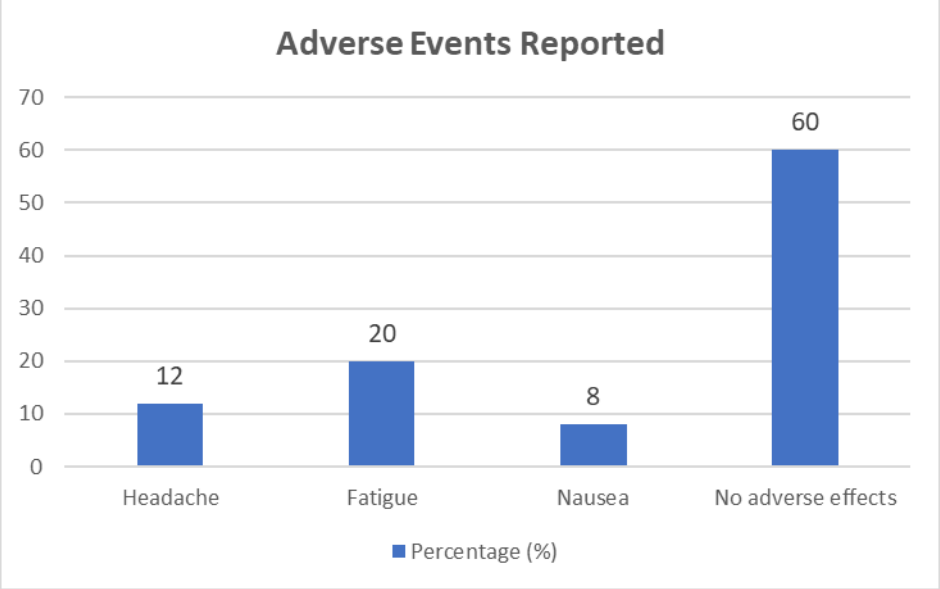
I/II) were seen in 20% of patients, and another 20% demonstrated early cirrhotic changes, suggesting progression to chronic liver disease in a notable proportion. These imaging findings correlate with the biochemical evidence of hepatic involvement and emphasize the importance of early detection and intervention in HCV infection.

Table 5: Treatment Regimen and Adverse Events

Regimen Used	Number of Patients (n)	Percentage (%)
Sofosbuvir + Velpatasvir (12 weeks)	45	90.0
Sofosbuvir + Daclatasvir (12 weeks)	5	10.0

Adverse Events Reported	Number of Patients (n)	Percentage (%)
Headache	6	12.0
Fatigue	10	20.0
Nausea	4	8.0
No adverse effects	30	60.0



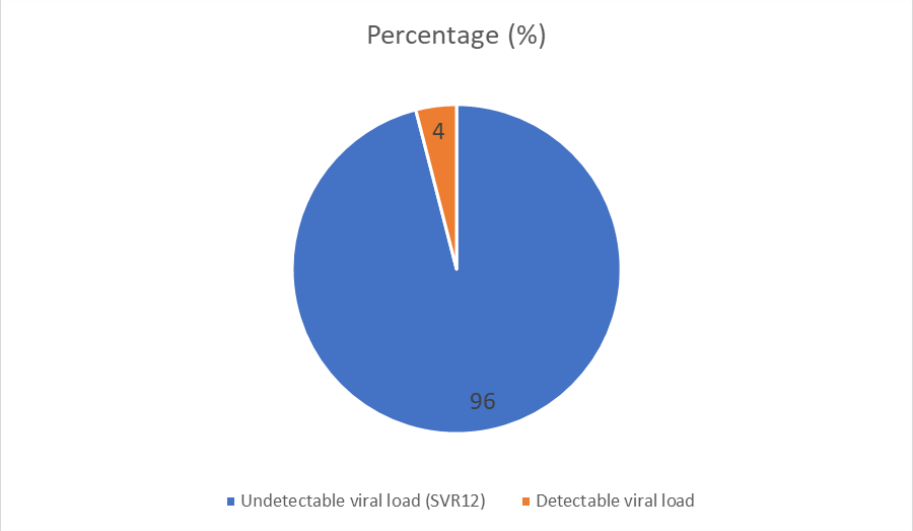


In this study, 90% of patients received the Sofosbuvir + Velpatasvir regimen, while 10% were treated with Sofosbuvir + Daclatasvir, both for a duration of 12 weeks. The treatment was generally well tolerated; 60% of patients reported no adverse effects.

The most common side effects included fatigue (20%), headache (12%), and nausea (8%), all of which were mild and self-limiting.

Table 6: Treatment Outcome at 12 Weeks (SVR12)

Outcome	Frequency (n)	Percentage (%)
Undetectable viral load (SVR12)	48	96.0
Detectable viral load	2	4.0



At the end of the 12-week follow-up, 96% of patients achieved Sustained Virologic Response (SVR12), indicating a high treatment success rate, while only 4% had a detectable viral load, possibly due to poor adherence, resistance, or advanced disease.

IV. Discussion

This study was done to assess epidemiological characteristics, clinical features, laboratory profile, and treatment outcomes among patients with HCV infection at a tertiary care center in South India. The study included 50 treatment-naïve patients aged between 18 and 45 years.

In our study, the majority of patients (50%) were in the 26–35 age group, with a male predominance (64%). Similar age distribution and gender predominance were reported in a study by Goel et al. (2019), which analyzed national data and found HCV to be more prevalent in younger males due to behavioral and occupational exposure risks [2]. Occupationally, 40% of the participants were manual laborers—possibly due to higher exposure to non-sterile equipment or poor awareness regarding transmission risks.

Regarding risk factors, a significant proportion (40%) had no identifiable source of infection, consistent with other studies showing that a large number of HCV cases arise from unrecognized or asymptomatic exposures. History of transfusion (24%), dental procedures (20%), and IV drug use (16%) were commonly reported. These figures align with the findings from Desikan and Khan (2017), who reported similar prevalence of iatrogenic and behavioral risk factors in Indian populations [3].

Clinically, fatigue (70%) and abdominal pain (40%) were the most common symptoms, while 30% of the patients were asymptomatic. The high proportion of asymptomatic cases is typical for chronic HCV, as supported by Seeff et al. (2002) and WHO reports, which state that most people remain asymptomatic until significant liver damage has occurred [5].

The laboratory parameters showed elevated liver enzymes (ALT: 82.4 ± 35.2 U/L, AST: 76.1 ± 32.8 U/L), which is consistent with chronic hepatic inflammation. Bilirubin was mildly elevated in some cases (mean: 1.4 ± 0.7 mg/dL). These findings are consistent with Ghosh & Mishra (2017), who described liver enzyme elevation as a key biochemical hallmark of HCV-related liver injury [5].

Ultrasound imaging revealed early cirrhotic changes in 20% and fatty liver in another 20%. These findings highlight the disease progression and the need for timely diagnosis and intervention. In a modeling study by Blach et al. (2017), it was estimated that more than 20% of untreated HCV patients would progress to cirrhosis within 20 years, consistent with our ultrasound-based evidence of early chronic changes [1].

Regarding treatment, 90% received Sofosbuvir + Velpatasvir, while 10% were prescribed Sofosbuvir + Daclatasvir. These regimens are in line with national (NVHCP 2018) and international (EASL 2020) guidelines

for the management of chronic HCV. Side effects were minimal and manageable; fatigue (20%), headache (12%), and nausea (8%) were the most frequently reported adverse events—similar to the safety profile reported in trials like Feld et al. (2015), where DAAs were associated with high tolerability and minimal side effects [6].

Importantly, 96% of patients achieved SVR12, demonstrating an excellent treatment response. This finding is similar to that of Gupta et al. (2018), who reported >95% SVR in patients treated with generic DAAs in India [6]. This outcome reinforces the effectiveness of government-supplied, low-cost DAA regimens in the Indian setting.

Strengths and Limitations

The current study have practical insights on treatment outcomes and patient profile in a tertiary care center.

Limitations:

Small sample size, and short follow-up duration. Resistance profiling and liver fibrosis scoring (like FibroScan or APRI/FIB-4) were not included may provide indepth knowledge.

V. Conclusion

This study confirms that Hepatitis C infection predominantly affects young to middle-aged adults, often presents with non-specific or no symptoms, and can progress silently to chronic liver disease. Direct-Acting Antiviral therapy is highly effective and well-tolerated, achieving SVR12 in the majority of cases. Continued public health efforts toward screening, early diagnosis, and universal treatment access are crucial for HCV elimination in India.

References

[1] World Health Organization. Hepatitis C. Updated June 2022. Available From: Https://Www.Who.Int/News-Room/Fact-Sheets/Detail/Hepatitis-C
[2] Simmonds P. Genetic Diversity And Evolution Of Hepatitis C Virus—15 Years On. J Gen Virol. 2004;85(Pt 11):3173–88.
[3] Alter MJ. Epidemiology Of Hepatitis C Virus Infection. World J Gastroenterol. 2007;13(17):2436–2441.
[4] Chakravarti A, Dogra G, Verma V, Srivastava AP. Seroprevalence Of Hepatitis C Virus In Different Adult Population Groups In North India. Indian J Med Res. 2011;134(5):691–695.
[5] Seeff LB. Natural History Of Chronic Hepatitis C. Hepatology. 2002;36(5 Suppl 1):S35–S46.
[6] European Association For The Study Of The Liver. EASL Recommendations On Treatment Of Hepatitis C 2020. J Hepatol. 2020;73(5):1170–1218.
[7] Ministry Of Health And Family Welfare, Government Of India. National Viral Hepatitis Control Programme Operational Guidelines. 2018. Available From: Https://Main.Mohfw.Gov.In/
[8] Blach S, Et Al. The Burden Of Hepatitis C Virus Infection In Europe: An Overview. Lancet Gastroenterol Hepatol. 2017;2:161-176.
[9] Goel A, Et Al. Hepatitis C Virus Infection: Prevalence, Burden, And Management In The South Asian Region. J Gastroenterol Hepatol. 2019;34:321-329.
[10] Desikan P, Khan Z. Seroprevalence And Genotypic Distribution Of Hepatitis C Virus In Indian Patients. Indian J Med Microbiol. 2017;35:332-339.
[11] Feld JJ, Et Al. Treatment Of Hepatitis C Virus Infection In Patients With Cirrhosis: A Systematic Review And Meta-Analysis. N Engl J Med. 2015;373(27):2599–2607.
[12] Seeff LB. Natural History Of Chronic Hepatitis C. Hepatology. 2002;36(5 Suppl 1):S35–S46.
[13] Gupta S, Et Al. Current Status Of Antiviral Treatment For Hepatitis C: A Systematic Review. J Viral Hepat. 2018;25:771-778.