

Clinical Study on Hepatitis C Virus Infection in Babylon, Iraq

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Abstract

Background: Hepatitis C virus (HCV) infection is the important and common cause of chronic liver disease, cirrhosis, and hepatocellular carcinoma. **Objective:** The objective of this study is to develop proper clinical care and conduct follow-up of HCV-infected patients, in addition to the natural history, morbidity, and risk factors of HCV. **Materials and Methods:** A retrospective study performed on a sample of 106 patients referred to the gastro intestinal tract center in Merjan Teaching hospital Babylon from January 2011 to January 2018. All the patients were assessed for clinical history, interviewed, and had a proper clinical examination to reflect demographic and some important epidemiologic data. **Results:** The clinical association of HCV infection according to age and gender, and age range (4–80 years) and the year (31–40) represent 25.5% of total studied cases, and the male-to-female ratio in predominant age group is 2:1. As seen in Table 5, increased number of patients were from urban areas than from rural regions. Those who work as shopkeepers or earner constitute 29.2%, followed by housewives 27.4%. Diabetes mellitus and hematologic manifestations are the main extrahepatic manifestations. Approximately 22.6% of the studied patients were asymptomatic and 57.5% had mild degree of hepatic fibrosis. **Conclusion:** All HCV-infected patients should be considered for treatment, and we noticed complete treatment response in 44.3% of studied patients, particularly in those treated with oral direct acting antiviral therapy.

Keywords: Clinical study and morbidity, HCV infection

INTRODUCTION

Hepatitis C virus (HCV) infection is a major health concern worldwide, as it is one of the major causes of chronic hepatitis associated with the risk of development of liver cirrhosis and hepatocellular carcinoma; in addition, it is considered a silent epidemic because most of the infected people are not aware of their disease and the mean of their exposure levels. The most common mode of spread of HCV is by intravenous injection or illicit drug abuse through injection and to a less extent via blood transfusion or hetero or homosexual spread.^[1] A rough estimate of the comparative risks of transmission through a needle stick is provided by the rule of threes: HBV is transmitted in 30% of exposures, HCV in 3%, and human immunodeficiency virus (HIV)-1 in 0.3%; these numbers are most likely influenced by the size of the inoculum, the size of the needle, and the depth of inoculation.^[2] The CDC now recommends one-time HCV testing for all adults (18 years and older) and all pregnant women during every pregnancy.

In 60%–80% of patients exposed to HCV infection, there is a chance of chronicity, and in 30%, there will be progress to liver cirrhosis within a period of two to three decades, and there is 2%–4% chance of hepatocellular carcinoma development per year.^[3]

In studies in Iraq, the incidence of HCV infection was 5.9:1000, which is higher than that reported by some other different studies.^[4] The aim of therapy of HCV infection is to provide eradication of the infection and prevention of complications. The end point of successful therapy is a sustained virologic response sustained virus response (SVR), which is defined as undetectable HCV RNA in serum 24 weeks after treatment has been stopped. The use of peginterferon and ribavirin has been the standard of care for patients with chronic HCV, regardless of the strain

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of the virus (genotypes 1, 2, 3, 4, 5, or 6). This regimen results in rates of SVR of 70%–80% among patients with HCV genotype 2 or 3 infection and rates of 45%–70% among patients with any of the other genotypes. Recently, INF free regimen and simple treatment regimen have been used to treat a large population with HCV chronic infection.^[5]

The control and prevention of HCV infection depends on distribution of HCV infection worldwide and the determination of its risk factors and assessment of factors that enhance disease progression. And due to the lack of a vaccine or some form of post-exposure prophylaxis, an accurate epidemiological assessment to plan primary prevention actions in any given population is essential and needs to be followed up.^[6]

The current study aimed to document the clinical aspects and certain demographic features of HCV infection in Babylon province, which provides help for control and prevention of HCV infection and guide future research studies.

MATERIALS AND METHODS

A total of 106 patients were referred to the gastro intestinal tract (GIT) center in Merjan Teaching Hospital from various medical units and healthcare centers in Babylon, and all the patients were tested by serologic assay for anti-HCV antibodies from January 2011 to January 2018 by third-generation ELISA for screening and confirmation of the presence of HCV exposure or clinical suspicion of chronic HCV infection. Clinical interviews and examination of data of age, gender, address, and occupation and profession of patients were carried out in the GIT unit. Acute HCV infection is rarely seen in clinical practice, and most of the patients with chronic HCV infection were asymptomatic or had mild symptoms before development of hepatic fibrosis. The main tools used in this study for assessment of severity and extent of liver fibrosis include non-invasive tests:

1. Level of transaminase enzymes
2. Blood picture including platelets count
3. The use of fibroscan
4. The use of ultrasound (U/S) and magnetic resonance imaging (MRI) (elastography with magnetic resonance imaging)

All the studied cases required virologic assays using quantitative real-time polymerase chain reaction (HCV RNA tests) for confirming infection and genotype status and monitoring therapy. Degree of liver injury was determined using mainly non-invasive methods of liver transaminase assays, blood profiling, liver ultrasonography, and fibroscan, and in few patients, invasive liver histopathology was carried out.

Statistical analysis includes calculation of chi square values in addition to estimation of mean and standard deviation of values. *P* value of <0.05 were considered statistically significant.

Standard deviation of values. *P* value less than 0.05 were considered statistically significant. Patient confidentiality and privacy were ensured, and verbal consent and written consent were obtained whenever indicated.

RESULTS

The age range in these patients is 4–80 years, with a mean age of 40.75 ± 15.33 years, as demonstrated in Table 1. In this study, the mean age of patients was 40.75 ± 15.33 years, and the predominant age of exposure to HCV infection = (21 – 40 years) was found in around 49% of cases.

The geographical distribution has been demonstrated in Table 2, the highest number of patients were from the Hilla center, and these patients represent urban population and higher probability of education.

Table 1: Hepatitis C patients in relation to age and gender

Variables	Number	%
Age of patient (years)		
4–10	2	1.9
11–20	4	3.8
21–30	24	22.6
31–40	27	25.5
41–50	22	20.8
51–60	17	16.0
61–70	6	5.7
71–80	4	3.8
Total	106	100.0
Gender		
Male	69	65.1
Female	37	34.9
Total	106	100.0
Male-to-female ratio	2:1	

Table 2: HCV patients in relation to geographical distribution

Address	Number	Percentage (%)
Hilla center	37	34.9
Mahaweel (Nael, Gbala, Haswa, and Eskandria)	28	26.4
Musaib	16	15.1
Hashmyia	18	17.0
Shomaly	2	1.9
Abugharak	2	1.9
Kifil (refugee)	3	2.8
Total	106	100.0

Table 3: HCV patients in relation to their occupation or profession of 106 cases

Profession	Number	Percentage (%)
Governmental employee	23	21.7
Shopkeeper, earner	31	29.2
House wife	29	27.4
Health care worker, nurses	4	3.8
Teacher and students	5	4.7
Child	2	1.9
Retired	5	4.7
Policeman	1	0.9
Farmer	6	5.7
Total	106	100.0

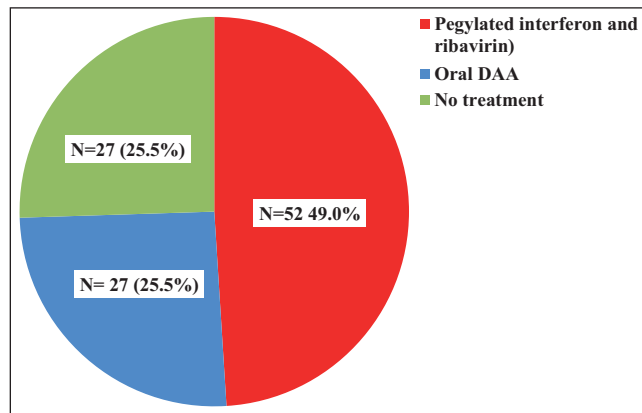
**Figure 1:** Distribution of patients according to the type of treatment

Table 3 demonstrates the studied patients in relation to their occupation or job, with more number of housewives and shopkeepers

During the course of the current study, it had been demonstrated that oral therapy has more benefits than parenteral therapy, as demonstrated in Figure 1.

DISCUSSION

Focaccia *et al.*, in a study on epidemiology of HCV infection in 1998, reported a prevalence of anti-HCV positivity of 1.42% in 1049 residents of São Paulo county.^[7] Higher prevalence was observed in individuals over 30 years of age, with the peak of 3.8% seen in the 50–59 years age group. Worldwide, different distinct epidemiological patterns were observed, one in USA and Australia, and highest age of exposure was observed between 30 and 39 years and lower prevalence in age below 20 years and age above 50 years; it seems similar to the present study. Another pattern was observed in Turkey, Spain, Italy, Japan, and China. The predominant age of exposure was between 40 and 50 years, which might indicate higher risk of infection in the far past. The last pattern is observed in Egypt, in which there is increase in number with age, and a large number of cases were observed in all age groups.^[8–12]

The gender difference in this study male-to-female ratio equal to 2:1, whereas in another study,^[4] it was mentioned that in all Iraqi governorates, the highest incidence of HCV infection was in the age group 15–45 years, and the lowest was in the age group 1–4 years. For the total of 576 new recorded infections of HCV, 296 were males and 280 were females, with male-to-female ratio of 1:1.1, and the HCV detection rate in males and females was nearly similar as the differences were statistically not significant, with a male-to-female ratio of 1:1.1; unfortunately it is difficult to compare this ratio with the incidence in previous years.

There is no screening for HCV antibodies as a universal program in all healthcare facilities in Iraq; moreover, the nongovernmental health care facilities including private clinics and hospitals are increasing substantially, and thus we should apply the trends of Anti-HCV antibody testing and screening on each patient consulting these healthcare facilities, particularly those above the age of 18 years, as a measure to control HCV transmission. The prevalence of HCV infection in Iraq is around 0.7%.^[13] In another study, the overall prevalence of HCV antibody was 0.8%,^[14] whereas the present study reported the seroprevalence of HCV, which indicates that HCV is found in >10% of patients infected with HBV worldwide. We also noticed that only two patients with chronic HCV infection have concomitant HBV infection.^[15]

We investigated the prevalence of the disease, but previous studies on the incidence of HCV infection in Iraq reported highest incidence rates recorded in three regions: Baghdad-Resafa, Diwaniya, and Sulaymaniyah, and they were 15.2:1000, 13.7:1000, and 13.2:1000, respectively; the lowest incidence rates were registered in Erbil, Diyala, and Najaf, and the results were 0, 0.32, and 0.53, respectively. The overall incidence rate among screened individuals in Iraq was 5.9:1000.^[4] In other countries, the incidence of thalassemia in patients in Iran was 4.2/1000.^[16]

In rural northern Italy, the incidence of HCV in adults is approximately 0.5/1000 inhabitants/year in 1996,^[17] while in France, an incidence of 0.05% new HCV infections/year was determined in patients undergoing chronic hemodialysis.^[18]

Table 3 represents the HCV patients in relation to their occupation or profession of 106 cases, which gives us a crude look to risk factors of exposure to HCV infection. It shows a higher number of patients in shopkeepers, employees, and housewives and to lesser extent in healthcare workers. These indicate that proper blood screening leads to reduction in HCV transmission by blood transfusion or blood product transfusion, but sharing of contaminated material by IV drug users is the greatest risk factor for transmission of the disease in the population, and in the last 30 years, use

of IV contaminated drugs was 70%–80% in developed countries.^[19,20] In this study, the prevalence of HCV infection is not higher among healthcare workers (3.8%) than in the rest of the population;^[21] needle-stick injuries in the healthcare setting continue to result in nosocomial spread of the virus. The rate of infection after needle piercing ranged from 0 to 10% in various studies. Rough estimation of the comparable risks of infection by the three hazardous viruses through needle prick injuries is provided by the rule of threes: HBV is transmitted in 30% of exposures, HCV in 3%, and HIV-1 in 0.3%.^[21-25]

Table 4 represents HCV patients in relation to year of diagnosis: 106 cases, and it seems to have no statistical significance, except during the year 2014, 26 cases (24.5%), and the higher number of cases might coincide with the emergence of direct acting oral antiviral drugs.

There are important extrahepatic manifestations of CV infection in addition to the stigma of chronic liver diseases [Table 5]; it had been noticed that the course of the disease is variable depending on the gender of the patient; it is better in females, and regarding the age of patients, the disease course is better in younger age; in addition, risk of disease progression is higher in alcoholics and in those with co-existence of other viruses including HIV and HBV infection. A clear pathophysiological role of all these manifestations is difficult to be established.^[26]

In developed and underdeveloped countries, there is a clear association between type 2 DM and chronic HCV infection, and the prevalence rate in North Americans, Europeans, and Middle Eastern people and Asians ranges from 13% to 33%, and it is estimated that 20% of chronic HCV patients will develop liver cirrhosis, and 50% of these cirrhotics will have type 2 diabetes mellitus; this is consistent with a study presented in a medical conference held by the Iraqi Medical Association conference in Baghdad during the year 2011. A paper was accepted in this conference as a poster, which considers that 50% of the studied cirrhotics are type 2 diabetics, as also in unpublished thesis,^[27] about prevalence of glucose abnormalities in patients with chronic HCV infection. A cross-sectional study of 146 patients included 70

chronic HCV infection cases and 76 with chronic HBV infection. Their age range was from 6 years to 82 years; certain presumed risk factors were determined by proper history taking and the presence of glucose abnormalities determined by fasting and random blood glucose measurements. HCV infection was detected by using third-generation ELISA tests. In 70 patients with chronic HCV infection, 32% had diabetes or impaired GTT. Chronic HCV infection is directly associated with insulin resistance, independent of the visceral adipose tissue area or metabolic syndrome. This is the first report to demonstrate the direct involvement of HCV and resistance to insulin, in patients with chronic HCV infection.^[28]

Some direct acting antivirals (DAAs) appear to work well on all HCV genotypes. Others work on only one or some. There is a higher chance for if you have genotype 1. Genotype 3 may not respond as well to DAAs alone.^[29]

Table 6 demonstrates the correlation to severity and hepatic fibrosis in the studied patients: Assessment of severity and extent of liver fibrosis:^[30]

We depend mainly on non-invasive tests (as most of our patients are unwilling of undergoing live biopsy) including

1. Level of transaminase enzymes
2. Blood profiling including platelet count
3. The use of fibroscan
4. The use of U/S and MRI (elastography with magnetic resonance imaging)

Most of the studied patients had mild to moderate fibrosis. FibroScan fibrosis scores cover five possible stages of liver damage, from none or mild all the way to severe fibrosis and cirrhosis, as shown in Table 6.

Table 4: HCV patients in relation to year of diagnosis 106 cases

Year of diagnosis	Frequency	Percentage (%)
2011	15	14.2
2012	9	8.5
2013	24	22.6
2014	26	24.5
2015	20	18.9
2016	6	5.7
2017	6	5.7
Total	106	100.0

Table 5: In relation to extrahepatic manifestations

Extrahepatic manifestation	Frequency	Percentage (%)
Diabetes mellitus	17	39.5
Thyroid (hypothyroidism; goiter)	1	2.3
Gall bladder stones	2	4.7
Blood (anemia, leucopenia, and thrombocytopenia)	11	25.6
Skin (rash, itching, and vitiligo)	1	2.3
Hypoalbuminemia	2	4.7
Renal manifestation, nephritis	2	4.7
Cardiac manifestation	2	4.7
Pulmonary manifestation	2	4.7
Lymphoma NHL	1	2.3
Prolonged INR	2	4.7
Total	43	100.0

F0–F1: No scarring, no scarring and asymptomatic with frequency of 24 patients (22.6%). F2: Mild with some scarring, frequency of 61 patients (57.5%)

F3: Moderate scarring, frequency of 17 patients (16%).

F4: Severe scarring and fibrosis (cirrhosis), frequency of four patients (3.8%) In mild-to-moderate fibrosis and scarring, we might be able to prevent worsening of fibrosis by doing the following measures:

1. The use of antiviral treatment
2. control of obesity and dyslipidemia
3. Eat healthy diet of high biologic value
4. Exercises and activities
5. stop alcohol

Table 6: Severity of chronic HCV infection to degree of fibrosis

Severity and fibrosis	Frequency	Percentage (%)
Asymptomatic	24	22.6
Mild	61	57.5
Moderate	17	16.0
Severe	4	3.8
Total	106	100.0

Table 7: In relation to response

Response	Frequency	Percentage (%)
Complete or good response	47	44.3
Incomplete response	23	21.7
No response	6	5.7
Follow up	30	28.3
Total	106	100.0

Regarding treatment of HCV patients in Babylon, Table 7 and Figures 1 and 2 demonstrate the number of treated patients, their response rate, and the duration and types of antiviral therapy. While treatment options for chronic hepatitis C (CHC) in adults are well set, CHC in children will remain part of the global burden of HCV until development of equally preventive measures, as we have two children with CHC reported in this study.^[27,31-33]

All over the world, only about one in three people who have HCV and health insurance get treatment for chronic HCV infection, and a number of patients delay treatment or avoid it altogether.^[34] The causes are complex: being symptom-free and high cost; some centers have limited access to DAA therapy. For these reasons, HCV screening for people of age 18–79 years must be published even in asymptomatics.^[35]

Tables 7 and 8 and Figure 2 demonstrate the response to therapy in the studied patients, and we had noticed that in 44.3% of the patients, SVR sustained virologic response fulfilled, which means that 12 weeks or more after completion of therapy, RNA testing could not detect the HCV in the blood, which indicates complete cure. Incomplete response of 21.7% and 5.7% no response had been noticed in patients receiving interferon and ribavirin treatment as a result of their side effects and duration of treatment and also noticed in patients with genotype 1 and in patients with interrupted follow-up. In 30% of patients receiving therapy, we mentioned that these patients need follow-up due to shortage or paucity of DAA therapy or the need of combination therapy, and all these 30% of patient were expected to have SVR on follow-up.^[36-39]

Table 8: The association between response and study variable

Study variables	Response to therapy				P value
	Complete	Incomplete	No response	Follow up	
Age (years)					
<30	11 (23.4)	0 (0.0)	1 (16.7)	13 (43.3)	<0.001*
30–50	28 (59.6)	11 (47.8)	0 (0.0)	12 (40.0)	
50–70	6 (12.8)	11 (47.8)	5 (83.3)	3 (10.0)	
≥70	2 (4.2)	1 (4.4)	0 (0.0)	2 (6.7)	
Total	47 (100.0)	23 (100.0)	6 (100.0)	30 (100.0)	
Severity and fibrosis					
Asymptomatic	5 (10.6)	2 (8.7)	1 (16.7)	16 (53.3)	<0.001*
Mild	35 (74.5)	14 (60.9)	0 (0.0)	12 (40.0)	
Moderate	7 (14.9)	5 (21.7)	4 (66.7)	1 (3.3)	
Severe	0 (0.0)	2 (8.7)	1 (16.7)	1 (3.3)	
Total	47 (100.0)	23 (100.0)	6 (100.0)	30 (100.0)	
Type of treatment					
Pegylated interferon and ribavirin	20 (40%)	21 (95.4)	5 (50.0)	6 (20.0)	<0.001*
Oral DAA	27 (54%)	1 (4.6)	0 (33.3)	0 (6.7)	
No treatment	3 (6.4)	0 (0)	1 (16.7)	22 (73.3)	
Total	50 (100.0)	22 (100.0)	6 (100.0)	28 (100.0)	

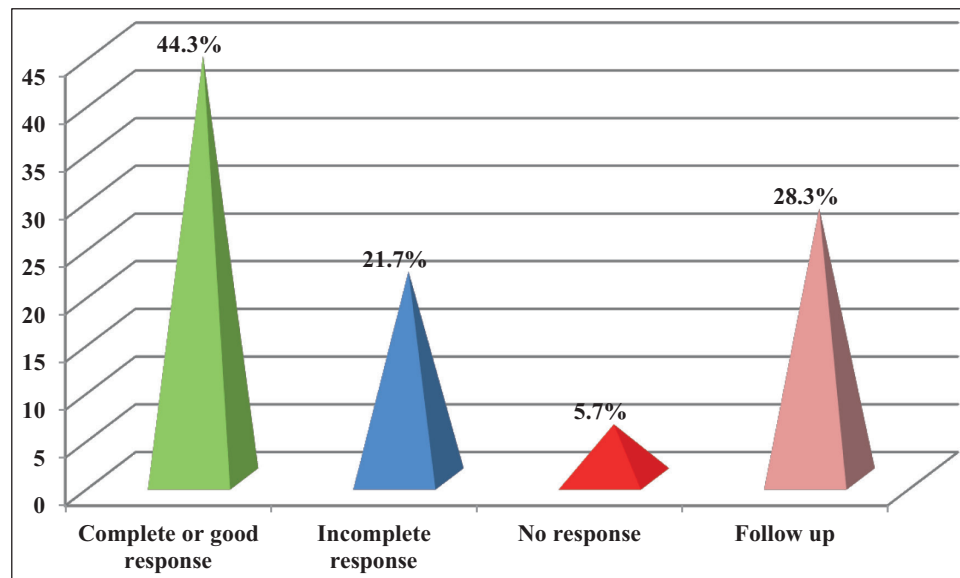


Figure 2: Distribution of patients according to type of response to therapy

Table 9: Types of therapy and its duration³⁹

Therapy	No	Response Rate	Duration
Pegylated interferon and ribavirin time 2011–2015	52	Overall, across genotypes, 60% viral clearance—and up to 80% viral clearance in genotypes 2 and 3	6–12 months
Oral DAA *after 2014	27	Overall, across genotypes, over 90% viral clearance and Sustained viral response	8–12 weeks

*Types of oral direct acting antiviral (DAA) used in the treatment of 27 patients

Sofosbuvir (single drug)

Sofosbuvir/ledipasvir (Harvoni)

Sofosbuvir/velpatasvir (Epclusa)

Table 8 demonstrates that a good response rate is observed in patient below 40 years of age (number 28 (59.6%)), and this is consistent with another study, which states that other adverse predictive factors affecting the efficacy of HCV treatment include liver fibrosis and cirrhosis, age ≤ 40 years, and the use of DAA therapy [Table 9].^[13,14,40]

During September 2014, five drug groups were approved for treatment of HCV all over the world.^[40–43]

1. Standard Interferon therapy or pegylated INF
2. Ribavirin
3. Three protease inhibitors (boceprevir, simeprevir, and telaprevir)
4. Nucleotide analog and polymerase inhibitor (sofosbuvir)
5. Over 25 new drugs or combination in clinical development: (two nucleotide polymerase inhibitors; six non-nucleoside polymerase inhibitors; eight non-structured protein inhibitors; seven protease inhibitors; one micro-RNA targeting compound and several fixed-dose combinations).

CONCLUSION

In conclusion, HCV infection is more likely to occur in the age group of 21–40 years. The results further indicate that a person's place of birth and residence could determine their HCV status. Although hematological abnormalities observed in this study were widespread among infected participants, they could indicate the side effects of the present treatment. This study also indicates the need for a larger study to ascertain the extent of HCV infections in Iraq. We recommend proper screening of HCV antibodies in those above the age of 18 years to below 80 years, and it should be mandatory in risk groups.

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Conflicts of interest

There are no conflicts of interest.

Declaration of patient consent

Patient confidentiality and privacy were ensured, and verbal consent and written consent were obtained whenever indicated.

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