

## Quality of Life among Hepatitis C Virus Patients Undergoing Direct Acting Antivirals



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### 1.ABSTRACT

**Background:** Hepatitis C virus (HCV) is a health issue that affects a significant proportion of the global population. HCV infection is a leading cause of cirrhosis, liver failure, and hepatocellular carcinoma. The new generation of oral direct-acting antivirals (DDAs) has transformed the treatment of hepatitis C virus infection, demonstrating both high efficacy and high tolerability, it is extremely effective and safe. **Aim:** This study aimed to assess quality of life among hepatitis C virus patients undergoing Direct Acting Antivirals. **Method:** Descriptive research design was utilized, included 150 HCV patients undergoing DDAs at Specialty Medical Hospital, Mansoura International Hospital and Bilqas Central Hospital. Data was collected by using two tools, structured interviewing questionnaire and the Chronic -Liver -Disease -Questionnaire. **Results:** fatigue was the most affected quality of life domain among our study subjects, the majority of our subject reported presence of fatigue all of the time. Activity was the followed quality of life domain affected. Bodily pain was the most affected symptoms in systemic symptom domain. Having problems with concentration was the most affected symptoms in emotional function domain. Abdominal symptoms and worry were the least affected quality of life domains among our subjects. **Recommendations:** Fatigue and activity were the highly problems that faced our study subject so, assessment and management for fatigue and activity should be done for those patients. Bodily pain was the most affected symptom related to systemic symptoms domains among our subjects so, assessment and management of these symptoms are very essential. Further researches should be done on larger and randomized selected sample to generalize the results. Developing fatigue intervention program for this population is highly recommended. Pain relieving measure program should be done for this population.

**Keywords:** - Direct Acting Antivirals, Hepatitis C virus, Quality of life

### 2.Introduction

Hepatitis C virus is one of the most significant causes of liver-related death and the most common indication for liver transplantation. Approximately 130-170 million people, or 3% of the world's population, are chronically infected with HCV. It is a major public health problem, with an estimated 3-4 million people infected each year worldwide (Kuna, Jakab, Smolic, Wu & Smolic, 2019). The highest rate of hepatitis C virus infection is found in Egypt., having a high antibody prevalence among people between the ages of 15 and 59 of about 10% and viremic prevalence of 7%, with almost all infections due to genotype 4. This burden required policymakers to develop effective therapeutic measures with a strong commitment. As a result, there is now the world's biggest nationwide HCV treatment programme. All

resource-constrained nations with HCV-related issues can learn from the program's successes and challenges (Elsharkawy, et al., (2018). The Global Health Sector Strategy for the eradication of viral hepatitis as a public health issue was approved by the 69th World Health Assembly in 2016. By 2030, the Global Health Sector Strategy and the World Health Organization (WHO) defined impact targets of a 90% decrease in chronic incidence and a 65% decrease in mortality. (Blach & Sanai, 2019). Interferon (INF) was the first step in treatment of HCV. Despite the fact that interferon targets the HCV virus by stimulating the immune system, which has a wide range of functions, IFN treatment has a number of adverse effects that make patients less likely to adhere to antiviral medication. Therefore, current advancements in medicine are

focused on developing INF-free, shorter-duration treatments with less side effects (**Bhattacharjee, Singh, Das, Chaudhuri & Mukhopadhyay, 2021**). The release of an effective direct antiviral drugs (DAAs) showed dramatical change in HCV treatment. Before the development of DAAs, hepatitis C was treated with a variety of treatment approaches, including INF, but none of these approaches was successful in improving patient-centered outcomes. DAAs interfere with viral replication by focusing on particular nonstructural viral proteins. DAAs is the oral medication which have been associated with improved efficacy, safety, tolerability, and shorter durations. So, The WHO suggested a number of IFN-free regimens, including combinations of sofosbuvir, simeprevir and ledipasvir and daclatasvir. which achieve the best health-related quality of life for HCV patients (**Wang, et al., 2019**). Direct Acting Antivirals have SVR rates above 97-98% and are safe and effective medications. The overall quality of life and psychological health of adult patients with chronic HCV infection do not appear to be negatively impacted by DAAs treatment therapy, but rather improved (**Bertino, et al., 2020**). It's the role of nurse and health care providers to educate and encourage HCV patients' compliance in and commitment to HCV therapy. So, formalized patient education has been demonstrated to increase understanding of HCV and make HCV management and coordination easier which result in best quality of life for those HCV patients (**Fokuo, et al., 2020**).

### 2.1 Significance of study:

Hepatitis C virus is a global public health crisis that affects a significant proportion of the global population. Chronic hepatitis C virus infection is a leading cause of cirrhosis, liver failure, and hepatocellular carcinoma. HCV infection remains one of the most prevalent bloodborne viral infections worldwide and is a leading cause of death from infectious disease globally. The recent introduction of direct-acting antivirals has revolutionized HCV therapy and made viral cure, which is associated with improved quality of life. The vast majority of HCV-infected patients can be cured with current DAAs treatment. The goal of the treatment is to eradicate HCV RNA, predictable by attainment of a sustained virologic response. It has been demonstrated that the elimination of HCV is linked to advantages such lower overall mortality, decreased healthcare utilization and increased quality of life. quality of life is a key component in the evaluation of any therapeutic intervention. It may be more relevant to

the appearance of symptoms on those patients so, the detection of these symptoms appears to be important when the patients' health status perception has to be considered. Therefore, it was deemed necessary to conduct this study to assess quality of life among Hepatitis C Virus Patients Undergoing DAAs.

### 2.2 Aim of the study

This study aimed to assess quality of life among hepatitis C virus patients undergoing Direct Acting Antivirals.

### 2.3 Research questions: -

- **RQ1:** Is DAAs has effect on quality of life of HCV patients undergoing DAAs?
- **RQ2:** What are the factors affecting quality of life of HCV patients undergoing DAAs?

## 3. Method

### 3.1 Study Design:

Descriptive research design was utilized to achieve the goal of the current study.

### 3.2 Study Setting:

This study was carried at the virology units at Specialty Medical Hospital, Mansoura University, Mansoura International Hospital and Bilqas Central Hospital. Those setting were well prepared to improve the service in Dakahlia government and the surrounding areas.

### 3.3 Subjects:

A convenient sample of 150 patients for a period of time from beginning of January 2021 to the end of April 2021. patients in previously mentioned setting fulfilling the following criteria: adult patients with HCV with RNA positivity, undergoing DAAs, started the medication DAAs for at least two months ago, willing to participate in the study and include group (1) of patients easy to treat. With exclusion of patients who were unconscious and Psychiatric patients.

### 3.4 Tools of Data Collection

Two tools were utilized to gather data for this research:

**Tool I:** Structured Interviewing Questionnaire, the researchers created this tool after studying relevant current national and international literature. It was consisted of two main parts:

**Part 1:** Demographic characteristics.

**Part 2:** Medical Data Sheet.

**Tool II:** Chronic Liver Disease Questionnaire (CLDQ), this tool was used to assess individuals with chronic liver disease's quality of life. developed by (**Younossi, Guyatt, Kiwi, Boparai,**

and King, 1999). The objective of this questionnaire is to know how patients have felt during the previous two months from the beginning of the treatment. The following six domains are represented by the 29 entries in this CLDQ: (abdominal symptoms, systemic symptoms fatigue, activity, emotional function and worry).

**Scoring system:** The scores for each domain were added to generate a total score, which ranged from (29-145) from the worst to the best quality of life. These six domains have 5 Likert scale starting from (1-5) and distributed as follow: {All of the above (1) - Most of the above (2) - Some of the above (3) - A little of the above (4) - None of the above (5)}. The total quality of life score with good results gives 145 degree and the worst result gives 29 degrees.

### 3.5 Validity and reliability:

**Validity:** was done for the study tools (1 & 2) to determine whether the tools covered the aim of the current study. Five experts from the Faculty of Nursing, Medical Surgical Nursing, at Mansoura University revised the study tools for its relevance, comprehensiveness, applicability and clarity. After that, the necessary modifications were done accordingly.

**Reliability:** was tested to assess how well the items used fit together conceptually and to determine if each item on the research instruments measures the same variable. It was tested by using Cronbach's Coefficient Alpha test and it was 0.85-0.92.

### 3.6 Pilot study:

A pilot study was conducted on 15 patients (10%) of study sample in order to test the feasibility, objectivity, clarity, and applicability of the study tools, as well as to identify challenges that may arise during application of the study and to estimate the amount of time required for data collection, necessary modification was made, and as a result, those patients from the pilot study were excluded from the actual study sample.

### 3.7 Ethical Consideration:

From the nursing faculty of Mansoura University, formal permission was acquired. The Mansoura University Faculty of Nursing's Research Ethical Committee gave ethical permission. The accountable administrator of each institution granted official clearance for the study to be carried out. After full and clear explanation of the study's purpose and its nature, patients who agreed to participate a verbal consent was obtained from them. Every participant was made aware of the study's voluntary nature and their freedom to discontinue participation at any time.

### 3.8 Field work:

The researcher made assurance of the patients was carried out to assure that participants have inclusion and excluded from the exclusion criteria. The researcher made assurance of the time of starting DAAs to confirm that all patients had started their treatment for at least two months ago. The researcher began by introducing herself to the patients before thoroughly outlining the concept and purpose of the study. A comfortable, private place in the waiting area was chosen for the interview. The researcher gave the sheet to patients who could read and write and with wellbeing condition to participate and fill the sheet. The researcher read the sheet to patients who weren't able to read and write or had any health conditions that could restrain them from writing or reading. The researcher attended to the virology units only three days (Sunday, Monday, Tuesday) a week distributed on the three setting. The majority of patients agreed to participate in the current study and just a small minority of patients declined.

### 4. Results:

**Table (1):** Show distribution the participants according to their demographic characteristics. The highest percentage of studied subjects (75.4%) were from the age group of 40 years to more than 50 years old. There was more than half (56%) of them were females. In relation to marital status, most of studied subjects (82%) were married. The intermediate education represents more than one third (44.7%) of the studied subjects. More than two third (71.3%) of the studied subjects reported no enough monthly income from the point of view of them.

**Table (2):** Represents studied patients' responses regarding abdominal symptoms. There were about (18.7%) of studied subjects reported feeling of abdominal bloating and abdominal pain all of the time. While, (19.3%) of them reported feeling of abdominal discomfort most of the time.

**Table (3):** Show patient's responses regarding fatigue domain. It is observed from this table that most of studied subjects reported presence of fatigue all of the time. The majority (83.3%) of them reported feeling drowsy, (78.7%) of them reported bothered by having decreased strength, (78%) of them reported being tired or fatigued, (65.3%) of them reported decreased level of energy and (54%) reported of them feeling sleepy during the day.

**Table (4):** Show studied subjects' responses regarding Systemic symptoms domain. About two third (68.7%) of our study subjects reported

presence of body pain all of the time. While (16.7) reported having dry mouth all of the time, and only (16%) of the studied subjects reported having shortness of breath all of the time.

**Table (5):** Shows studied subjects’s responses regarding activity domain. Most of studied subjects reported all of the time toward activity domain. About two third (68.7%) of study subjects reported bothering by limitation of diet all of the time. (60%) of them reported difficulty in carrying heavy objects all of the time while one third (34.7%) of them reported inability to eat as much as they want all of the time.

**Table (6):** Represents studied subjects’s responses regarding emotional function domain. The majority (63.3%) of studied subjects reported having problems with concentration all of the time.

While (60.7%) of them reported being irritable all of the time.

**Table (7):** Represent studied subjects’s responses regarding worry domain. Only (17.3%) of studied subjects reported felling worry about impact of their liver disease on their families all of the time. While, about one quadrant (26.7%) of studied subjects reported worrying about getting worse little of the time.

**Table (8):** Shows total score of studied subjects’s responses regarding Chronic Liver Disease Questionnaire Domains. It showed that the total mean of Chronic Liver Disease Questionnaire Domains of studied subjects was 85.26%. The highest percentage was 72.92% for Systemic symptoms and followed by Worry which represented 71.92%. On the others hand fatigue was the lowest category (31.64%).

**Table (1): (Demographic Characteristics of studied patients) N= 150**

Characteristics	No	%
Age (y)		
20 ≤30	10	6.7
30 ≤ 40	27	18
40 ≤ 50	55	36.7
> 51	58	38.7
Gender		
Male	66	44
Female	84	56
Marital status		
Single	9	6
Married	123	82
Widow	18	12
Education Level		
Illiterate	48	32
Intermediate education	67	44.7
Secondary School	21	14
University education	14	9.3
Work Status		
None	77	51.3
Manual Work	47	31.3
Office work	26	17.3
Monthly Income		
Enough	43	28.7
Not Enough	107	71.3

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Table (2): - Distribution of the research subjects according on their reported abdominal symptoms domain of Chronic Liver Disease Questionnaire (During the last two months ago).

Questions	All of the time	Most of the time	Some of the time	A little of the time	None of the time
1. How much of the time during the last two weeks have you been troubled by a feeling of abdominal bloating?	18.7	8.7	16	22	34.7
5. How much of the time during the last two weeks have you experienced abdominal pain?	18.7	19.3	17.3	21.3	23.3
17. How much of the time during the last two weeks have you been troubled by a feeling of abdominal discomfort?	8.7	19.3	18	18	36

Table (3): - Distribution of studied patients according to the reported fatigue domain of Chronic Liver Disease Questionnaire (During the last two months ago).

Questions	All of the time	Most of the time	Some of the time	A little of the time	None of the time
2. How much of the time have you been tired or fatigued during the last two weeks?	78	12.7	.7	6.7	2
4. How often during the last two weeks have you felt sleepy during the day?	54	14	19.3	8.7	4
8. How much of the time in the last two weeks have you been bothered by having decreased strength?	78.7	9.3	6	4	2
11. How often during the last two weeks have you felt a decreased level of energy?	65.3	11.3	11.3	4	8
13. How often during the last two weeks have you felt drowsy?	83.3	7.3	4	1.3	4

Table (4): Distribution of the research subjects according on their reported Systemic symptoms domain of Chronic Liver Disease Questionnaire (During the last two months ago).

Questions	All of the time	Most of the time	Some of the time	A little of the time	None of the time
3. How much of the time during the last two weeks have you experienced bodily pain?	68.7	22	4.7	3.3	1.3
6. How much of the time during the last two weeks has shortness of breath been a problem for you in your daily activities?	16	7.3	8.7	10.7	57.3
21. How often during the last two weeks have you had muscle cramps?	6.7	1.3	2	11.3	78.7
23. How much of the time during the last two weeks have you had a dry mouth?	16.7	10	3.3	18	52
27. How much of the time have you been troubled by itching during the last two weeks?	6	2.7	.7	8.7	82

Table (5): Distribution of the research subjects according on their reported Activity domain of Chronic Liver Disease Questionnaire (During the last two months ago).

Questions	All of the time	Most of the time	Some of the time	A little of the time	None of the time
7. How much of the time during the last two weeks have you not been able to eat as much as you would like?	34.7	20	12	7.3	26
9. How often during the last two weeks have you had trouble lifting or carrying heavy objects?	60	24	8	5.3	2.7
14. How much of the time during the last two weeks have you been bothered by a limitation of your diet?	68.7	16	5.3	4	6

Table (6): Distribution of the research subjects according on their reported Emotional function domain of Chronic Liver Disease Questionnaire (During the last two months ago).

Questions	All of the time	Most of the time	Some of the time	A little of the time	None of the time
10. How often during the last two weeks have you felt anxious?	8.7	15.3	20.7	37.3	18
12. How much of the time during the last two weeks have you felt unhappy?	11.3	6.7	20	26	36
15. How often during the last two weeks have you been irritable?	60.7	11.3	10	9.3	8.7
16. How much of the time during the last two weeks have you had difficulty sleeping at night?	10.7	13.3	23.3	21.3	31.3
19. How much of the time during the last two weeks have you had mood swings?	10.7	16	20.7	22.7	30
20. How much of the time during the last two weeks have you been unable to fall asleep at night?	8.7	15.4	26	22	28
24. How much of the time during the last two weeks have you felt depressed?	5.3	4.7	22	32.7	35.3
26. How much of the time during the last two weeks have you had problems concentrating?	63.3	18.7	8	2	8

Table (7): Distribution of the research subjects according on their reported Worry domain of Chronic Liver Disease Questionnaire (During the last two months ago).

Questions	All of the time	Most of the time	Some of the time	A little of the time	None of the time
18. How much of the time during the last two weeks have you been worried about the impact your liver disease has on your family?	17.3	22	22	14.7	24
22. How much of the time during the last two weeks have you been worried that your symptoms will develop into major problems?	14	10.7	17.3	22	36
25. How much of the time during the last two weeks have you been worried about your condition getting worse?	11.3	11.3	23.3	26.7	27.3
28. How much of the time during the last two weeks have you been worried about never feeling any better?	10	22.7	12	25.3	30
29. How much of the time during the last two weeks have you been concerned about the availability of a liver if you need a liver transplant?	4	5.3	2.7	16	72

Table (8): Descriptive Statistics of Chronic Liver Disease Questionnaire Domains N= 150

CLDQ Domains	Items No	Min	Max	Mean± SD	Percentage*
Abdominal symptom	3	3	15	10.10 ± 3.511	67.33
Fatigue	5	5	19	7.91± 3.27	31.64
Systemic symptoms (SS)	5	9	25	18.23 ± 3.558	72.92
Activity (AC)	3	3	12	5.99 ± 2.37	39.93
Emotional function (EF)	8	11	37	25.09 ± 5.44	62.97
Worry (WO)	5	8	25	17.98 ± 3.79	71.92
Total	29	50	120	85.26 ± 15.31	

**5.Discussion:**

One of the most widespread viruses is hepatitis C, which became an important public health problem recognized by the W H O. Approximately 10% to 20% of the chronic infected patients experience constant inflammation and developed liver cirrhosis and eventually hepatocellular carcinoma (**Chaudhari, Fouda, Sainu & Pappachan, 2021**).

**Demographic characteristics & medical data.**

As regard to age in our study, HCV was found in three quadrants of patients from the age group of 40 years to more than 50 years old. It's also observed that HCV percentage increase with age. This is may be because of aging increase the risk for HCV. Our findings are consistent with the research conducted by **Radwan, et al., (2019)** who performed his study on 22,632 patients between January 2014, and December 2015, in United States. His study stated that median age of their patients were 47 years old.

Concerning gender, in our study more than half of patients were females. This agreed with **chen, et al., (2017)**, who conducted his study from January 2013 and January 2017, in China with a total number of 56,627 patients, reported that males had a lower percentage of HCV than females particularly in genotype 1b and 2a in his study.

In relation to marital status, the study results showed that the majority of studied patients were married. This finding is supported by **Sultan, YacoobMayet, Alaqeel, & Al-Omar, (2018)**, his study reported that most of their participants were married. On the other hand, the majority of **Abebe, Alemnew, and Biset, (2020)** who contracted his study on 17,810 patients, in Nekemte Blood Bank, Western Oromia, Ethiopia and from the period of January 2015 to December 2019. His study showed that most of his patients were unmarried.

Regarding to the level of education, more than tow third in our study had intermediate education. This may be supported with **Crespo, et al., (2020)** who conducted his study on 12,246

participants recruited from July 2015 to April 2017 in Spain. His study reported that most of his study participants had middle-upper levels of education. Contrasted with, **Almezgagi, et al., (2020)** who fulfilled his study in Yemen. His study reported that most of his patients were illiterate, that's according to his study which performed in Al-Thawrah hospital, Yemen, from the period of May 2013 to April 2016 on 100 HCV patients.

In relation to monthly income, in our study there are more than two third of participants reported no enough monthly income according to the point of view of them. In this respect, **Mahmoud, Abdallah, Mahmoud and Taha, (2020)** who conducted his study on 120 patients, at Benha Fever Hospital, Egypt. His study clarified that most of his study participants had no enough monthly income.

**Assessment of the quality of life of HCV patients undergoing DAAs according to chronic liver disease questionnaire.**

As regard to abdominal symptoms, the current study revealed that there was a decrease in the presence of abdominal symptoms, which include a feeling of abdominal bloating, abdominal pain and abdominal discomfort. It's hand on hand with **Serper, et al., (2021)**, his study reported that there was an improvement in their patient's abdominal symptoms especially abdominal pain. On the other hand, **Sung, et al., (2020)**, his study reported that their patients did not have significant improvement in physical functioning and abdominal symptoms.

According to fatigue domain, most of our study subjects reported being tired or fatigued, feeling sleepy, bothering by having decreased strength, feeling decreased level of energy and feeling drowsy all of the time. This finding is agreed with **Indolfi, et al., (2020)**, his study stated that headache and fatigue were the most common adverse events that appeared on their subjects. On the other hand, **Mir, Kahveci, Ibdah, and Tahan, (2017)**, reported that most of his Patients reported enhancements in their fatigue, emotional, general

health, and mental well-being after DAAs therapy. In relation to systemic symptoms, which include (presence of body pain, shortness of breath, muscle cramps, dryness of mouth and itching). In present study, about two third of our study subjects reported presence of body pain. On the other hand, **Yi, et al., (2020)**, who conducted his study in Eastern Taiwan, on a total number of 158 patients. His study reported an improvement in body pain and physical functioning in most of his participants.

Concerning activity domain, in present study, activity domains was affected in most of its items which include (bothering by limitation of their diet, having trouble lifting or carrying heavy objects, inability to eat as much as they would like). About two third of our subjects reported all of the time, toward bothering by limitation of their diet. Also, most of our subjects reported having trouble lifting or carrying heavy objects. Additionally, about one third of them reported inability to eat as much as they would like all of the time. Our result is inconsistent with **Salama, et al., (2022)** his study reported that there was an improvement in his subject's physical function, fatigue, cognitive impairment, and quality of life.

Concerning worry domain, our current study showed that most of our subjects reported decrease impacts toward most of worry domain items. This finding is agreed with **Rei, Rocha & Pedroto, (2017)**, who conducted his study between April and October 2015, his study reported that lower symptoms were observed for worry, fatigue, and emotional function domains in his study subjects.

#### 6. Conclusion:

Based on the finding of the present study, it can be concluded that direct acting antivirals affected on our subject's quality of life according to CLDQ domains which contains (abdominal symptoms, fatigue, systemic symptoms, activity, emotional function, worry). Fatigue was the most affected domain in our subjects, the majority of our subject reported presence of fatigue all of the time. Activity was the followed quality of life domain affected. Bodily pain was the most affected symptoms in systemic symptom domains. Having problems with concentration was the most affected symptoms in emotional function domain. Abdominal symptoms and worry were the least affected quality of life domains in our subjects. Additionally, there was a relationship between CLDQ domains with each other. Also, there's a relationship between gender and quality of life domains such as abdominal symptoms, activity, fatigue, emotional function and worry. Finally, the

present study showed that there was a relationship between job and quality of life domains such as activity, fatigue and emotional functions domain.

#### 7. Recommendation:

In the light of the findings of the current study, the following recommendations are Suggested:

- Fatigue and activity were the highly problems that faced our study subject so, assessment and management for fatigue and activity should be done for those patients.
- Bodily pain was the most affected symptom related to systemic symptoms domains in our subjects so, assessment and management of this symptoms is very essential.
- Having problems with concentration was the most affected symptoms in emotional function domain. That's why we should assess those subjects' cognitive and emotional function.

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