

Quality of Life of Chronic Hepatitis C Patients Receiving Sovaldi Treatment Regimen at Sharq Almadina Hospital in Alexandria

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Abstract

Background: Hepatitis C virus (HCV) infection is a worldwide public health problem, affecting about 3% of the world's population. The introduction of sofosbuvir (Sovaldi) markedly changed therapeutic outcomes. The assessment of HRQoL in HCV patients under treatment might help to better understand the effect of treatment on the patient's quality of life. **Aim:** The study was conducted to assess the quality of life of chronic hepatitis C patients receiving Sovaldi at the outpatient hepatology clinic in Sharq Almadina hospital. **Patients and Methods:** A cross-sectional survey was conducted among chronic hepatitis C patients receiving Sovaldi treatment regimen for at least 3 months. Data was collected from the studied CHCV patients using face-to-face interviews including personal & sociodemographic characteristics, The chronic liver disease questionnaire (CLDQ) to assess health-related quality of life, and the translated Arabic version of the short-form (SF 36) generic quality of life questionnaire. In addition, reviewing the medical records of studied CHCV patients to collect data about their laboratory findings was done. **Results:** More than two-thirds of studied patients (69.1%) discovered the disease during the National Egyptian Campaign. The overall median value of SF-36Q items was 53.19 indicating a poor HRQoL. There were significant positive correlations between the majority of SF-36Q individual domain scores and that for CLDQ $P < 0.001$ as well as the total scores. **Conclusions:** There were significant positive correlations between the majority of SF-36Q individual domain scores and that for CLDQ as well as the total scores.

Keywords: HCV, Sovaldi, QoL

Introduction

Hepatitis C virus infection (HCV) is a resource-consuming health problem, where there is an increase of 2.8% in its seroprevalence over the previous years, accounting for about 185 million cases⁽¹⁾. HCV can lead to acute and chronic infections, its severity

ranges from mild disease for a few weeks to a severe lifetime illness. Acute HCV infection is asymptomatic in most cases and is only-very rarely- associated with serious disease. Within 6 months of infection, around 34% of patients recovered spontaneously without treatment. The remaining patients develop chronic HCV infection⁽²⁾.

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Globally, viral hepatitis was ranked as the 7th leading cause of mortality. With hepatitis C virus is responsible for around half of this mortality⁽³⁾. Egypt is one of the most affected countries by HCV. World Health Organization (WHO) has classified Egypt as having the highest prevalence of Hepatitis C virus worldwide, with about 20% of blood donors testing positive for HCV. Egypt has the highest hepatitis C prevalence with thousands of people dying yearly due to major liver complications like liver failure and liver cancer^(4,5). Two-thirds of seropositive Egyptian patients are chronically infected and need treatment⁽⁶⁾. Even though the historical anti-Schistosoma parenteral treatment campaigns were accused of this high prevalence of HCV, around two-thirds of the positive cases nowadays acquired the infection from healthcare settings⁽⁷⁾. The prevalence of HCV antibodies among adults 15–59 years is 14.7% in 2009 and 10.0% in 2015 according to the Egyptian Demographic and Health Surveys (EDHS)⁽⁷⁾. Lowering of the prevalence of seropositivity might be due to population aging, improved infection control practices as well as the availability of directly acting antiviral drugs. In addition to migration and death of HCV-positive persons⁽⁸⁾. Mostly, patients with chronic HCV infection need antiviral medications. The first aim of treatment is clearance of infection, and finally sustained virological response (SVR). Six months after the beginning of treatment HCV-RNA counts that reach less than 50 international units per milliliter; may show sustained treatment with recurrence only in about 5% of patients^(9,12). Therefore, with increased morbidity and mortality associated with CHCV infection, it is critical to achieving viral clearance associated with significantly reduced rates of liver failure, progression of fibrosis, and liver-related deaths among CHCV patients⁽¹³⁾. Globally, the development of direct-acting antiviral

(DAA) agents, has transformed the treatment of HCV infection. These DAA targets viral proteins and cellular processes that are essential to viral replication⁽¹⁴⁾. The HCV Model of Care (MOC) was established in 2006 through the National Committee for Control of Viral Hepatitis (NCCVH) to design a national strategic plan to control HCV infection. This plan demonstrates policies and procedures for patient care service delivery. The Egyptian initiative campaign of national treatment for viral hepatitis is considered one of the most fruitful and effective public health initiatives worldwide. The NCCVH showed success to implement a robust strategy to control viral hepatitis in Egypt⁽⁹⁾. Once the DAA was registered in Egypt, the Ministry of State for Administrative Development developed a web-based online registration system (www.nccvh.org.eg)^(10,11). Health-related quality of life (HRQoL) is the patients' perception of the disease's effect on their daily life, as well as their psychological and social well-being. Therefore, it is used as the gold standard to measure patients' own experiences with their disease journey⁽¹⁵⁾. While antiviral treatment can improve the rate of liver-related deaths, associated side effects can have a negative impact on HRQoL⁽¹⁶⁾. The previous anti-HCV treatment with interferon and ribavirin had a further negative impact on patients' HRQoL due to substantial side effects. Well evidenced side effects of interferon are often described as an influenza-like episode, including fever, myalgia, and headache. Interferon (IFN)-mediated bone marrow suppression can produce pancytopenia. Neurological, psychological, and gastrointestinal manifestations were documented^(17,18). There have been no studies to date on how Egyptian HCV patients who have received the new DAAs feel about their HRQoL. As a result, this is the first study to assess a variety of patient-related outcomes (PROs), such as

health-related quality of life (HRQoL), physical, mental health status (i.e., depression, anxiety, and stress), and perceived social support, among HCV patients receiving new DAAs therapy regimens, either interferon-free or interferon-containing regimen. The purpose of this manuscript was to assess the health-related quality of life of chronic hepatitis C patients receiving Sovaldi containing regimen in terms of physical, mental, and social functioning in Sharq Almadina hospital.

Patients and Methods

This cross-sectional study was carried out on 165 HCV patients receiving Sovaldi treatment. Chronic hepatitis C patients above 18 years of age of both genders who received oral Sovaldi containing regimen (Sofosbuvir 400 mg and daclatasvir 60 mg once daily) for at least three months (12 weeks) and agreed to participate in the study were included. While Patients with adjuvant hepatitis B virus (HBV) infection and those who have liver cirrhosis, hepatocellular carcinoma, or chronic liver diseases of other causes were excluded from the study. A minimum sample of 165 chronic hepatitis C patients receiving Sovaldi is needed to assess their quality of life using CLDQ (chronic liver disease questionnaire) based on Chang et al 2014⁽¹⁸⁻²⁰⁾. The sample size was estimated using PASS program version 20 at %5 level of significance and 80% power⁽¹⁸⁻²¹⁾. A systematic random sampling method was used to obtain the required sample during the period of the fieldwork.

Data collection tools

A. *Patient interview*: All patients in the study were interviewed to collect data using

- A structured interview format: it included data about patients' personal

and socio-demographic characteristics, their medical and family history as well as detailed treatment history for hepatitis C infection namely history of receiving Sovaldi injection before oral Sovaldi, the timing of receiving oral Sovaldi containing regimen, treatment adherence, side effects of medications and perceived improvement after treatment.

- *The chronic liver disease quality of life questionnaire (CLDQ)*: It is an instrument that is disease-specific, used for measuring health-related quality of life (HRQoL) in patients with chronic liver disease (CLD). The questionnaire consists of six domains namely Abdominal Symptoms (AS) 3 items, Fatigue (FA) 5 items, Systemic Symptoms (SS) 5 items, Activity (AC) 3 items, Emotional Function (EF) 8 items, and Worry (WO) 5 items with a total score of 29 items. The chronic liver disease questionnaire (CLDQ) was the first liver-specific questionnaire developed in 1999^(19,22,23). It has been translated into many languages for cross-cultural use and proved to be a successful and valid tool for HRQOL measurement in patients with chronic liver disease. The Arabic form was used. A score was measured for each item, and the scores ranged from 1 (the most impaired) to 7 that had the least symptoms, indicating a good prognosis. The total score was calculated as the average of the 29 domains obtaining a total score ranging from 1 to 7.
- *The translated Arabic version of the short-form (SF-36) generic quality of life questionnaire⁽²⁴⁾*: The SF-36 questionnaire consists of eight scales

- namely physical functioning (10 items), role-physical (4 items), bodily pain (2 items) health (5 items), vitality (4 items), social functioning (2 items), role-emotional (3 items), and mental health (5 items). In addition to a single item that indicates perceived change in health. Scoring of the questionnaire was done in two steps:

Step I: All questions were scored on a numeric scale using a scoring key. All items are scored so that a high score defines a more favorable health state. Then each item is scored on a 0 to 100 scale (transformed score)

Step II: The scores from those items that express each domain of functional health state are then averaged, for a final score for each of the 8 dimensions assessed.

- *Record review:* Reviewing the medical records of studied chronic hepatitis C patients to obtain their data at the beginning of treatment and the results of laboratory investigations including baseline investigations and those at 12 weeks after starting Sovaldi treatment namely liver function tests and complete blood count. In addition to the results of the PCR test (HCV- RNA counts).

A pilot study was carried out to test the data collection tools, assess the feasibility of data collection, and estimate the average time needed for collecting the data. It included 15 patients. Their data were not included in the final data for analysis.

Ethical Considerations

An informed verbal and written consent was obtained from all studied patients after explaining the nature, steps, and aim of the

study. Patients were informed that participation is voluntary and patients' right for refusing participation was respected. Privacy and confidentiality of data obtained were ensured all through the conduction of the research. The study was conducted after approval of the Medical Ethics Committee of Alexandria Faculty of Medicine.

Statistical Analysis

IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) was used for the analysis of data. The Kolmogorov-Smirnov test was used to test the normality of distribution. Quantitative data were described using range (minimum and maximum), mean, standard deviation if were normally distributed however median and interquartile range (IQR) were used to describe variables that were not normally distributed. Significant results were made when the p-value was less than 5%.

Results

1. Sociodemographic characteristics of CHCV patients

As regard gender, more than half of all studied CHCV patients (58.8%) were females, while just more than two-fifths of them (41.2%) were males. Concerning the age of the studied CHCV patients, it ranged from 23.0 to 70.0 years, with a mean age of 49.29 ± 14.12 years, less than one-third of them (29.7%) were ≥ 60 years, near to a quarter of CHCV patients (24.2 %) were 50- <60 years, one fifth (20.0%) were 40- <50 years, (13.9%) were <30 years and (12.1%) were 30- <40 years. The mean age of female patients was lower than that of male patients (47.26 ± 13.89 years and 52.19 ± 14.02 years respectively, $p = 0.010$, (Table 1). The majority of the studied CHCV patients, (81.2%) lived in urban areas. Insignificantly, there was a slightly higher proportion of male patients who were living in urban areas than female patients (86.8% and

77.3 % respectively, $p=0.126$). Concerning the level of education, around half of studied CHCV patients (50.9%) were illiterate/

read and write, 22.4% had secondary education, 17.0% had basic education, and 9.7% had a university education and above.

Table 1: Description of some sociodemographic characteristics for the studied Patients

Personal information	CHCV patients (n=165)		Male (n = 68)		Female (n =97)		Test of sig.	p
	No.	%	No.	%	No.	%		
Gender								
Male	68	41.2						
Female	97	58.8						
Age(years)							$\chi^2=22.2^*$	<0.001*
<30	23	13.9	3	4.4	20	20.6		
30-<40	20	12.1	14	20.6	6	6.2		
40-<50	33	20.0	8	11.8	25	25.8		
50-<60	40	24.2	16	23.5	24	24.7		
≥60	49	29.7	27	39.7	22	22.7		
Min. – Max.	23.0 – 70.0		29–70		23–70			
Mean ±SD.	49.29 ± 14.12		52.1 ± 14.0		47.2 ± 3.8		U=2521*	0.010*
Median (IQR)	51 (37– 60)		54 (40-5)		47 (37-58)			
Residency							$\chi^2=2.337$	0.126
Urban	134	81.2	59	86.8	75	77.3		
Rural	31	18.8	9	13.2	22	22.7		
Level of education							$\chi^2=7.97^*$	0.047*
Illiterate/ Read and write	84	50.9	26	38.2	58	59.8		
Basic education	28	17	15	22.1	13	13.4		
Secondary	37	22.4	20	29.4	17	17.5		
University & above	16	9.7	7	10.3	9	9.3		
Marital status							$\chi^2=22.63^*$	<0.001*
Single	20	12.1	14	20.6	6	6.2		
Married	123	74.5	54	79.4	69	71.1		
Divorced / Widow	22	13.3	0	0.0	22	22.7		
Working status							$\chi^2=120.59^*$	$^{MC}p<0.001^*$
Currently working	54	32.7	47	69.1	7	7.2		
Housewife	84	50.9	0	0.0	84	86.6		
Don't work	27	16.4	21	30.9	6	6.2		
Smoking status							$\chi^2=66.339^*$	$^{MC}p<0.001^*$
Current	41	24.8	37	54.4	4	4.1		
Ex-smoker	4	2.4	4	5.9	0	0.0		
Nonsmoker	120	72.7	27	39.7	93	95.9		
Intravenous drug use							$\chi^2=15.185^*$	$^{FEP}p<0.001^*$
Ex IVD	10	14.7	10	14.7	0	0.0		
Nonintravenous addiction	155	93.9	58	85.3	97	100.0		

A higher proportion of female patients (59.8%) was illiterate/ read and write compared to male patients in this aspect

(38.2%, $p=0.047$). Marital status showed that 12.1% were single and 13.3% were divorced / Widow. A significantly slightly

higher proportion of male patients were married compared to married female patients (79.4% and 71.1% respectively). All the divorced/ widow patients (13.3%) were among females. Single male patients showed a higher proportion than single female patients (20.6% and 6.2 % respectively). Differences between male and female patients were statistically significant ($P < 0.001$). Concerning the working status about half of CHCV patients (50.9%) were housewives, one-third of them were currently working (32.7%) and (16.4%) did not work. Most male patients (69.1%) were currently working compared to (7.2%) of cur-

rently working female patients ($p < 0.001$).

Lifestyle habits of CHCV patients

About three-fourths of CHCV patients (72.7%) were non-smokers, around a quarter (24.8%) were current smokers and only (2.4%) were ex-smokers. A significantly higher proportion of male patients were currently smoking than female patients (54.4% and 4.1% respectively, $p < 0.001$). Furthermore, a minority of CHCV patients (14.7%) were ex- intravenous drug addicts. All the female patients (100%) were non-intravenous drug addicts compared to 85.3% of male patients ($p < 0.001$) (Table 1).

Table 2: Distribution of chronic HCV patients according to scores of CLDQ (n = 165)

CLDQ items	All studied chronic HCV patients n=165		
	Min. – Max.	Mean \pm SD.	Median (IQR).
Abdominal symptoms (AS)	1.0 – 7.0	4.49 \pm 1.88	5.0(3.0 – 6.0)
Fatigue (FA)	1.0 – 7.0	4.41 \pm 1.55	4.6(3.0 – 5.6)
Systemic symptoms (SS)	1.0 – 7.0	5.05 \pm 1.46	5.4(4.2– 6.2)
Activity (AC)	2.33 – 7.0	5.81 \pm 1.46	6.7(4.7– 7.0)
Emotional Function (EF)	1.0 – 7.0	4.48 \pm 1.56	4.8(3.3– 5.6)
Worry (WO)	1.0 – 7.0	3.64 \pm 2.36	3.2(1.0– 6.2)
Overall CLDQ	1.67 – 7.0	4.59 \pm 1.28	4.7(3.8 – 5.4)

2. Quality of life of chronic liver disease patients receiving sovaldi treatment using CLDQ and SF36 questionnaire

Table (2) shows that the overall mean value of CLDQ items was (4.59 \pm 1.28) indicating fair HRQoL. The highest mean value (best HRQoL) was for activity domain (5.81 \pm 1.46), followed by a mean value of systemic symptoms (5.05 \pm 1.46), then nearly similar mean value, of abdominal symptoms (4.49 \pm 1.88), emotional function (4.48 \pm 1.56) and fatigue domains (4.41 \pm 1.55). The lowest mean value (worst HRQoL) was for the worry domain (3.64 \pm 2.36). The overall mean score of CLDQ for male patients was insignificantly slightly higher than that for female patients (4.64

\pm 1.37 and 4.55 \pm 1.22 respectively), $P = 0.640$. Moreover, the overall mean score value was the highest (better HRQoL) for those patients in the age group 50- <60 years (4.77 \pm 1.18). It was nearly equal to those of the age group 30-<40 years and <30 years (4.71 \pm 1.33 and 4.70 \pm 1.28 respectively). The lowest mean score (poor HRQoL) (4.25 \pm 1.13) was noticed among the age group 40-<50 years. These results were found to be statistically insignificant, $P = 0.474$. Table (3). Concerning residency, insignificantly the overall mean score of CLDQ was found to be slightly higher for those patients who were living in urban (4.60 \pm 1.27) than those who were living in rural (4.54 \pm 1.34), $P = 0.810$.

Table 3: The overall CLDQ mean score and sociodemographic data of chronic HCV patients (n = 165)						
Parameter	N	overall CLDQ mean score CHCV patients			Test of Sig.	P
		Min. – Max.	Mean ± SD.	Median		
Gender						
Male	68	1.67 – 6.54	4.64 ± 1.37	4.77	t=0.468	0.640
Female	97	1.67 – 7.0	4.55 ± 1.22	4.50		
Age (years)						
<30	23	2.63 – 7.0	4.70 ± 1.28	4.58	F=0.885	0.474
30-<40	20	2.63 – 6.54	4.71 ± 1.33	4.75		
40-<50	33	1.67 – 6.29	4.25 ± 1.13	4.25		
50-<60	40	1.67 – 7.0	4.77 ± 1.18	4.79		
≥60	49	1.67 – 7.0	4.57 ± 1.42	4.67		
Residency						
Urban	134	1.67 – 7.0	4.60 ± 1.27	4.67	t=0.241	0.810
Rural	31	1.67 – 7.0	4.54 ± 1.34	4.42		
Living alone						
Yes	21	1.67 – 7.0	4.36 ± 1.42	4.25	t=0.866	0.388
No	144	1.67 – 7.0	4.62 ± 1.26	4.67		
Level of education						
Illiterate/ Read and write	84	1.67 – 7.0	4.58 ± 1.35	4.50	F=0.018	0.997
Basic education	28	1.67 – 6.54	4.56 ± 1.47	4.46		
Secondary	37	1.83 – 6.33	4.61 ± 1.10	4.75		
University & above	16	3.21 – 6.29	4.64 ± 0.98	4.63		
Marital status						
Single	20	1.83 – 7.0	4.95 ± 1.59	5.33	F=1.060	0.349
Married	123	1.67 – 7.0	4.56 ± 1.23	4.67		
Divorced / Widow	22	1.67 – 7.0	4.40 ± 1.22	4.25		
Working status						
Currently working	54	1.67 – 6.33	4.43 ± 1.29	4.63	F=0.931	0.396
Housewife	84	1.67 – 7.0	4.61 ± 1.24	4.50		
Don't work	27	1.83 – 6.54	4.84 ± 1.38	5.0		
Income						
500-1000 LE	11	3.46 – 7.0	4.94 ± 1.01	5.0	F=0.674	0.511
1000-1500 LE	84	1.67 – 7.0	4.63 ± 1.33	4.63		
More than 2000 LE	70	1.67 – 6.54	4.49 ± 1.25	4.63		
Smoking						
Current smoker	41	1.67 – 6.54	4.53 ± 1.42	4.58	F=1.164	0.315
Ex-smoker	4	4.50 – 6.33	5.54 ± 0.94	5.67		
Nonsmoker	120	1.67 – 7.0	4.58 ± 1.23	4.63		
IV drug addiction						
Ex-IV addict	10	2.63 – 6.54	4.92 ± 1.55	5.48	t=0.858	0.392
Non-IV addict	155	1.67 – 7.0	4.57 ± 1.26	4.58		

The overall mean score for patients who were living alone (4.36±1.4) was in signifi-

cantly lower than those who were not living alone (4.62±1.2), p =0.38 (table 3).

Table 4: The overall CLDQ mean score and Sovaldi treatment in CHCV patients (n = 165)						
Parameter	N	overall CLDQ mean score of CHCV patients			t	P
		Min. – Max.	Mean ± SD.	Median		
SVR (HCV- RNA < 50 IU/mL)						
Yes	161	1.67 – 7.0	4.61 ± 1.27	4.67	1.601	0.111
No	4	1.67 – 5.04	3.58 ± 1.40	3.81		
History of SOVALDI injection						
Yes	7	2.75 – 5.38	4.31 ± 0.96	4.13	0.590	0.556
No	158	1.67 – 7.0	4.60 ± 1.29	4.67		
Improvement after SOVALDI injection						
Yes	3	2.75 – 4.88	3.78 ± 1.06	3.71	1.353	0.234
No	4	3.96 – 5.38	4.71 ± 0.77	4.75		
Poor adherence to intake of oral SOVALDI						
Yes	31	1.67 – 6.54	4.59 ± 1.42	4.75	0.001	0.999
No	134	1.67 – 7.0	4.59 ± 1.25	4.58		
Regular follow up visits						
Yes	151	1.67 – 7.0	4.59 ± 1.23	4.58	0.026	0.979
No	14	1.67 – 6.54	4.58 ± 1.76	4.77		
Compliance with the dietary recommendations						
Yes	146	1.67 – 7.0	4.57 ± 1.23	4.58	0.583	0.561
No	19	1.67 – 6.54	4.75 ± 1.62	5.0		
Side effects of oral sovaldi treatment						
Yes	69	1.67 – 7.0	4.74 ± 1.15	4.75	1.257	0.211
No	96	1.67 – 7.0	4.48 ± 1.36	4.46		
Psychological support from HC provider						
Yes	73	1.67 – 7.0	4.63 ± 1.22	4.67	0.343	0.732
No	92	1.67 – 7.0	4.56 ± 1.33	4.58		
Psychological and social support from family members						
Yes	140	1.67 – 7.0	4.57 ± 1.28	4.58	0.337	0.737
No	25	1.83 – 6.54	4.67 ± 1.26	4.75		
Health education from HC providers						
Yes	71	1.67 – 7.0	4.59 ± 1.17	4.67	0.039	0.969
No	94	1.67 – 7.0	4.59 ± 1.36	4.63		
GH improvement compared to previous 6 mos						
Improved	103	1.67 – 7.0	4.53 ± 1.28	4.58	0.821	0.413
Not improved	62	1.83 – 7.0	4.69 ± 1.29	4.75		

Regarding the level of education. The overall mean score of CLDQ was insignificantly the

highest for patients who had a university education and above (4.64 ± 0.98) and the low

est for patients who had basic education (4.56 ± 1.47), $P=0.997$. However, the overall mean score value of CLDQ was insignificantly the highest for the single patients (4.95 ± 1.59), $P=0.349$. The overall mean score value of CLDQ was higher for patients who do not work (4.84 ± 1.38) than for housewives (4.61 ± 1.24) and currently working patients (4.43 ± 1.29). Furthermore, The overall mean score of CLDQ was the highest for patients who had income from 500-1000 pounds/ monthly (4.94 ± 1.01) and the lowest for those whose income was more than 2000 pounds/ monthly (4.49 ± 1.25). These results were found to be statistically insignificant (Table 3). Table 3 indicates that the overall mean score of CLDQ was insignificantly the lowest for currently smoking patients (4.53 ± 1.42) and the highest for Ex-smokers patients (5.54 ± 0.94), $P=0.315$. However, the overall mean score of Ex-intravenous drug addiction patients was insignificantly higher than non-intravenous drug addiction patients (4.92 ± 1.55 and 4.57 ± 1.26 respectively), $P=0.392$. Table 3 illustrates that The overall mean score value was insignificantly higher for patients who had other associated chronic diseases (4.84 ± 1.23) than for patients without associated chronic diseases (4.44 ± 1.29), $P=0.055$. however, the overall mean score value was insignificantly the lowest for the patients whose duration of disease was <5years (4.54 ± 1.29) and the highest for patients with a duration of ≥ 10 years (5.03 ± 1.30), $P=0.392$. The overall mean score value was insignificantly lower for those who had a history of complications related to the disease before starting treatment (4.48 ± 1.21) than those who did not have any complications (4.88 ± 1.42), $P=0.071$. The overall mean score value was lower for patients with a history of receiving SOVALDI injection (4.31 ± 0.96) than for those who were not receiving it (4.60 ± 1.29). Furthermore,

the overall mean score value of patients who felt improvement after SOVALDI injection (3.78 ± 1.06) was lower than for those who did not feel improvement (4.71 ± 0.77). These results were found to be statistically insignificant. table (4). The overall mean score value of CLDQ was insignificantly nearly equal for those who had poor adherence to intake of oral SOVALDI treatment and those who did not have (4.59 ± 1.42 and 4.59 ± 1.25 respectively), $P = 0.999$. However, the overall mean score value was insignificantly slightly higher for regular follow-up visits patients (4.59 ± 1.23) than irregular follow-up visits one (4.58 ± 1.76), $P = 0.979$ (Table 4). Concerning compliance to dietary recommendations, insignificantly the overall mean score was lower for compliance patients (4.57 ± 1.23) than for non-compliance one (4.75 ± 1.62), $P=0.561$. The overall mean score value of CLDQ was insignificantly higher for patients who had oral SOVALDI regimen side effects (4.74 ± 1.15) than those without side effects (4.56 ± 1.33), $P=0.211$. Patients who had psychological support from health care providers showed a slightly higher overall mean score value of CLDQ than those who did not have such support (4.63 ± 1.22 and 4.56 ± 1.33 respectively), $P = 0.732$. Furthermore, the overall mean score of CLDQ was slightly lower for patients who had psychological and social support from family members (4.57 ± 1.28) than those who did not have (4.67 ± 1.26). These results were found to be statistically insignificant, $P = 0.737$. Table (4). The overall mean score value of CLDQ was insignificantly almost equal for patients who received health education about the disease from health care providers and those who did not receive health education about the disease, $p=0.969$.

b. Description of SF36 questionnaire total and domain scores among studied patients:

Figure (1) shows that the overall median value of SF-36Q items was 53.19 indicating a poor HRQoL. Regarding the various domain items of the SF-36Q, role limitations due to emotional problems recorded the highest median value (100.0) among all studied CHCV patients followed by the median value of physical functioning (80.0), social functioning (75.0), health change

(75.0) and pain (65.0). All these values indicate good HRQoL in these domains. On the other hand, the studied patients recorded the lowest median values in the following domains: energy/fatigue (40.0), emotional well-being (48.0), role limitations due to physical health, and general health perception equally (50.0 each). These values indicated poor HRQoL in these domains.

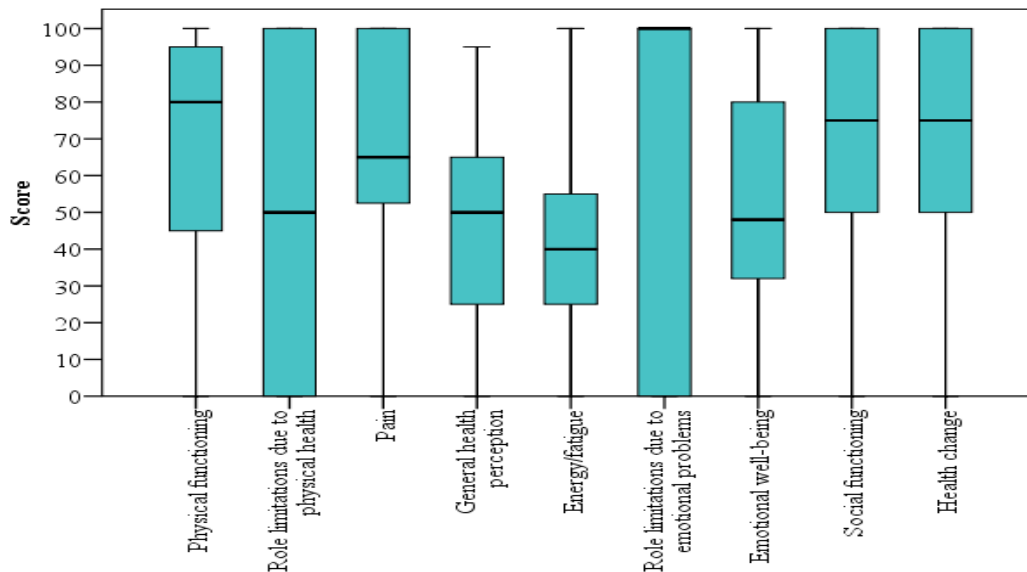


Figure 1: Distribution of studied chronic HCV patients according to domain scores of SF 36 questionnaire

B. Correlation between overall scores and various domains scores of SF-36Q items and CLDQ items of studied CHCV patients.

Figure (2) presents that there were significant positive correlations between the majority of SF-36Q individual domain scores and that for CLDQ $P < 0.001$ as well as total scores. The correlation between SF-36Q health change domain score with CLDQ overall scores and of abdominal symptoms, fatigue, systemic symptoms, and emotional function domains scores was found to be insignificant. Moreover, the magnitude of the correlation between the FA and EF subscales of CLDQ and SF-36Q scales was the highest.

Discussion

Health-related quality of life (HRQoL) can be used to assess patients' psychological, social, and physical well-being. Previous studies had shown that assessing HRQoL is of utmost importance to community health. It was reflected to be the gold standard to report pay papatients'xperiences with both illness and treatment⁽²⁵⁻²⁹⁾. HRQoL is an idea related to a person's subjective perception of his health in daily life.s. Moreover, It helps understand their expectations, concerns, aims, and living standards⁽²⁸⁾. The current study involved 165 papatientsuffering from HCV. Concern

ing the socio-demographic characteristics of the enrolled patients, as regards gender the present study revealed that more than

half of all studied CHCV patients (58.8%) were females.

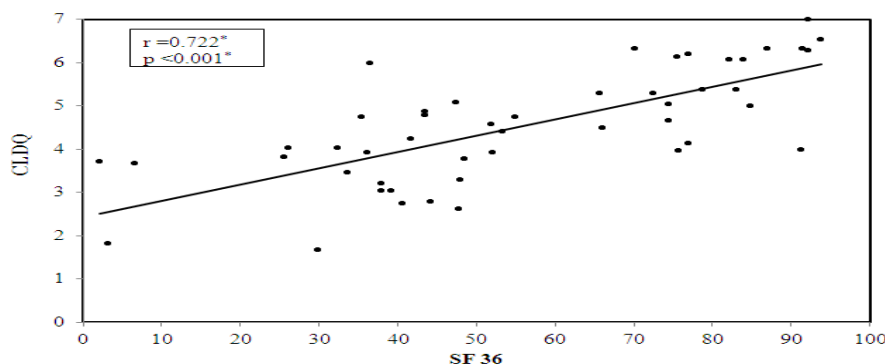


Figure2: Correlation between SF-36Q items' scores with CLDQ items scores of studied chronic HCV patients

These results were in agreement with a study conducted in China that showed that a total of 67.5% of the subjects were females⁽²⁷⁾. While it was inconsistent with a study carried out by Gamaleldin et al,(2016)⁽²⁸⁾ in Alexandria, Egypt in which the overall prevalence of anti-HCV-positive patients was higher among males (11.3%) than females (6.5%). Regarding residency, the majority of the studied CHCV patients, (81.2%) lived in urban areas. This is nearly consistent with a study conducted in Canada that showed that the majority of HCV cases (76.3%) referred to their center lived in urban areas⁽⁹⁾. And with that study done by Gamaleldin et al,(2016)⁽²⁸⁾ at Alexandria university showed that the prevalence of anti-HCV positive infection in urban areas was slightly higher (0.21%) than in rural areas (0.05%). On the contrary HCV prevalence in Egypt showed unequal geographic distribution, with the rural areas showing higher prevalence compared to urban sites, and in lower Egypt compared to the rest of the country⁽³⁰⁾. The parenteral anti-schistosomal treatment (PAT) initiatives were recognized

to be the major risk factor for this high prevalence of HCV in rural Egypt among elder patients⁽³⁰⁾. Also, another study conducted in China signifying that chronic viral hepatitis is more commonly seen in the rural areas than the urban areas of China⁽²⁷⁾. HCV infection is a social disease with about two-thirds of HVC positive individuals living in developing countries⁽¹⁾. The HCV epidemic in Egypt is socioeconomic. It is mostly prevalent among lower social and economic segments of the population⁽¹¹⁾. Furthermore, a minority of studied CHCV patients (14.7%) were ex- intravenous drug addicts. These results contradict that of a cohort's study in Canada which showed that intravenous drug intake was the most reported risk factor for HCV infection (61.1%), followed closely by intra-nasal drug intake (59.4%). Tattoos, high-risk sexual activity, and incarceration accounted for 47.8%, 44.8% and 40.2%, respectively⁽⁹⁾. However, Illicit drug users (IUDs), having an IUD partner, alcohol and tattooing constituted higher risks in Egypt than in her countries⁽¹²⁾. Regarding ways of discovery of the disease, more

than two-thirds of studied CHCV patients (69.1%) discovered the disease during the National Egyptian Campaign, while the west proportions discovered the disease either through accidental investigations or during analyzing job requirements or by the appearance of symptoms (13.3%, 10.9%, and 6.7% respectively). Results of the current study were consistent with a previous study that reported that discovery of HCV infection in Egypt is usually by chance or after being symptomatic due to liver disease appear. About 3% of the patients have been diagnosed actively⁽¹²⁾. These Egyptian initiative plans are assumed to have led to this increased HCV seropositive rates nowadays in the Nile Delta. There are mainly three reasons for this massive HCV transmission in this mass campaign. First, patients were subjected to many injections. Second, sterilization techniques were extremely poor. Finally extensive mistakes, including reuse of equipment^(30,31). Focusing on adherence of studied patients to oral Sovaldi treatment regimen, near to one-fifth of studied CHCV patients (18.8%) showed poor adherence to treatment. The most mentioned causes of poor adherence of studied CHCV patients were having many medications to take followed by thinking that the treatment is not useful, then being afraid of side effects (58.1%, 41.9%, and 22.6% respectively). These findings were in accordance with the results of four studies conducted to assess patients' references related to HCV treatment. They found that the most important patient-relevant outcome was overall treatment efficacy followed by risk of adverse events⁽³²⁻³⁴⁾. Concerning the effect of oral Sovaldi treatment regimen on biochemical parameters of studied CHCV patients it was found that there was a significant reduction in the median level of both ALT and AST (43 and 37 before treatment versus 24 and 26 after treatment), $P < 0.001$. Also significant reduction in the

mean hemoglobin level from 12.47 ± 1.73 before starting treatment to 11.82 ± 1.76 twelve weeks after treatment was noticed, $P < 0.001$. This finding was also supported by another study which reported that anemia is among the most commonly mentioned side effects of patients treated with RBV and SOF⁽³⁴⁾. In agreement with the current study finding a previous study conducted in Egypt illustrated that treatment of HCV patients with SOF-DCV with or without RBV was prematurely discontinued in only 1.5% of patients mostly due to hematological complication and decompensation⁽³⁵⁾. HRQoL aims to assess disabilities and effectiveness related to diseases. SF-36 is a generic health instrument that was used for the evaluation of HRQoL and also in clinical trials to study the effect of chronic disease on HRQoL⁽³⁵⁾. Concerning the results of the use of SF-36Q in the present study, it was found that the overall median value of SF-36Q items of the studied patients was 53.19 indicating an impairment in HRQoL. Regarding the various domain items of the SF-36 Q, role limitations due to emotional problems recorded the highest median value (100.0) among all studied CHCV patients followed by the median value of physical functioning (80.0), social functioning (75.0), health change (75.0) and pain (65.0). All these values indicate good HRQoL in these domains. On the other hand, the studied patients recorded the lowest median values in the following domains: energy/fatigue (40.0), emotional well-being (48.8), role limitations due to physical health, and general health perception equally (50.0 for each). These median values indicated poor HRQoL in these domains. Except for role limitation due to emotional problems, this finding is nearly consistent with a study carried out in Taiwan which revealed that antiviral-treated CHC patients experienced a marked decrease in scores on 6 scales of SF-36Q espe-

cially in the vitality, role physical, and emotional limitation scales with average scores (49.07 ± 22.87 , 37.50 ± 44.36 and 45.35 ± 47.03 respectively). The average score of the physical status was the highest with a score of 78.33 ± 20.29 ⁽²⁰⁾. Concerning the present results of the use of CLDQ to assess HRQoL of studied patients, it was found that the overall mean value of CLDQ items was (4.59 ± 1.28) indicating fair HRQoL. The highest mean values (best HRQoL) were for activity domain (5.81 ± 1.46), systemic symptoms (5.05 ± 1.46), then abdominal symptoms (4.49 ± 1.88), and emotional function (4.48 ± 1.56). The lowest mean values (worst HRQoL) were for the worry domain (3.64 ± 2.36) and fatigue domains (4.41 ± 1.55). These results contradicted the study conducted in China 2019, which showed that the WO dimension had the highest score in all CLDQ domains among the studied patients⁽²⁷⁾. But was consistent with both Taiwan and China study results regarding the scores of FA and EF dimensions of CLDQ which was found to be relatively low among the six dimensions^(20,27). Regarding the correlation between overall scores and various domains scores of SF-36Q items and CLDQ items of studied CHCV patients, it was found that scores of almost all domains of SF-36Q were positively correlated with that of CLDQ domains which were consistent with the study conducted in Taiwan 2014, which showed that all SF-36Q domains significantly correlated with all scores of CLDQ domains ($r > 0.20$)⁽³⁶⁾. and also, with other previous reports⁽³⁷⁻³⁹⁾. Moreover, the present study showed that the magnitude of the correlation between FA and EF subscales of CLDQ and SF-36Q scales was the highest. These findings concurred also with the result of the Taiwan study which indicated that fatigue is the most important factor leading to differences

in functioning and well-being in CHCV patients under antiviral treatment⁽³⁶⁾.

Conclusion

The overall median value of SF-36Q indicated a poor HRQoL, while the overall mean value of CLDQ reflected fair HRQoL. The highest scores were for activity, systemic and abdominal symptoms domains while the lowest was for worry and fatigue. A significant positive correlation was found between the majority of SF-36Q individual domain scores and both CLDQ and the total scores. Raising the awareness of HCW and family members of patients about CHCV (disease nature, impact of the disease and its treatment on all aspects of the patient's life) and declare their crucial role for relieving much of the patient's suffering and helping them to comply with the treatment and cope with disease burden is recommended.

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Availability of data and material: The data that support the findings of this study are available from the corresponding author upon request.

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