

Correlation between the patients with Hepatitis C Virus and their Health-Related Quality of Life

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Abstract

Background: Hepatitis C virus (HCV) infection is a global health problem and a major cause of morbidity and mortality. **The current study aimed** to assess the correlation between the patients with the hepatitis C virus and their health-related quality of life. Descriptive design was used. **Setting:** Carried out at liver virology outpatient. **Subject:** A convenient sample of two hundred adult patients with HCV newly received Sofosbuvir and Daclatasvir. **Tools:** Interview questioner and medical data sheet and Short-Form health survey (SF-36) questionnaire. **Results:** An improvement in the total quality of life this appear through 51.0% of hepatitis patients were poor in quality of life before treatment with Sofosbuvir and Daclatasvir medication while (62.0%) of them become excellent in quality of life after 3 months from treatment with highly statistically significant differences. Also, there was a fair negative association between the duration of disease of the studied patients with their total quality of life measured by short-form of health before administration of treatment with Sofosbuvir and Daclatasvir. **Conclusion:** The study concluded that the administration of Sofosbuvir and Daclatasvir for patients had positive effect on their quality of life especially for newly diagnosed patients. **Recommendation:** The study recommended that early screening for hepatitis C to begin early suitable treatment.

Keywords: Correlation, Hepatitis C Virus, Quality of Life

Introduction

Hepatitis C virus (HCV) infection is a global health problem and a major cause of morbidity and mortality (Faddan, et al., 2019), Egypt has the highest prevalence of Hepatitis C in the world. Overall, estimates of the HCV rate in the general population have ranged between 10 and 20 percent. Geographically, the Hepatitis C prevalence is higher in Lower Egypt (Nile Delta) than in Upper Egypt and lower in urban compared to rural areas. The economic burden is multiplied by the impact of HCV on health-related quality of life (HRQoL), appreciable at any stage of severity (Omran et al., 2018).

In Egypt, a cross-sectional survey of 21 governorates was done by El-Ghitany and Farghaly, (2019) to determine geospatial epidemiology of hepatitis C infection in Egypt found that the participant's age ranged from 14-90 years, the darkest spot of HCV infection in Menoufeya (37.8%) followed by Beni Suef (29.2%) and Minia (28.6%), and anti-HCV prevalence was higher among males.

Quality of Life (QOL) is a popular term that conveys an overall sense of well-being, including aspects of happiness and satisfaction with life as a whole. It is broad and subjective rather than specific and objective. The Complications of advanced liver disease such as encephalopathy, variceal hemorrhage, and ascites have been reported to negatively affect HRQoL. Extra-hepatic manifestations related to HCV as fatigue, irritability, depression, muscle pain, joint pain, and cognitive impairment may also influence the patient's psychological well-being and self-perceived health (Jain, et al., 2019).

Chronic infection with HCV has a profound effect on health-related quality of life (HRQoL) – with fatigue, depression, and neurocognitive deficits among the most common complaints. Neuropsychiatric symptoms have prompted research to determine whether the HCV acts within

the central nervous system. The replicating virus has been found in central nervous tissues, and changes in neurotransmitter levels in the frontal white matter of patients with chronic hepatitis C are correlated with impaired attention and concentration (Youssef, et al., 2017).

Although treatment-related adverse effects may dissuade people from starting therapy and reduce compliance with associated reductions in sustained viral response, for the majority of patients' viral clearance produces improvements in both HRQoL and long-term prognosis. Novel agents, with improved adverse effect profiles, may allow more patients to achieve a sustained viral response (Zainulabid, 2019).

The nurse must participate in educating individuals with HCV infection to improve HRQL through lifestyle changes initiated through behavioral modification. For example, education on the monitoring of symptoms such as fatigue, body pain, depression, and lack of ability to function effectively. Previous research has shown that individuals chronically infected with HCV respond to interventions focused on increasing knowledge and this, improves functional status and HRQL of individuals with chronic HCV (Youssef et al., 2017).

Significance of the Study:

According to a recent survey done in Egypt, 2015 found the prevalence rate among the population aged from 1-59 years (sample size 1,466) in Minia governorate was 9.0% of them have positive HCV antibody and 6.1% have positive HCV RNA test. HCV has a major impact on the quality of life and can cause patients significant distress. So, this study will be carried out to investigate the effect of HCV infection on HRQoL among patients. Multiple studies worldwide have shown that chronic hepatitis C is associated with considerable impairment of HRQoL (Ministry of Health and Population et al., 2015).

Aim of the study:

Assess the correlation between the patients with Hepatitis C Virus and their Health-Related Quality of Life.

Research question:

Is there a correlation between the patients with Hepatitis C Virus and their Health-Related Quality of Life impairment?

Research Design:

A Descriptive research design was utilized

Subjects

A convenient sample of two hundred adult patients with HCV newly received Sofosbuvir and Daclatasvir.

Inclusion criteria :

- Adult patient from 18- 60 years
- Conscious and oriented
- The patient has early stage of chronic hepatitis C
- Newly received Sofosbuvir and Daclatasvir medication.

Exclusion criteria:

- Musculoskeletal problems.
- Pregnant women.
- Other hepatitis viruses
- Immunocompromised diseases.
- Obesity (overweight 25 kg) and underweight patients.
- Patients with speech and mental disorders.

Setting :

The study was conducted in liver virology outpatients' clinic at Minia University Hospital and Fever Hospital related to ministry of health.

Study duration:

The total data collections were collected over period of 12 months starting from December 2018 to December 2019.

Data Collection Tools :

The current study data were collected by Two tools were designed, prepared, tested, and used for collecting data in this study after extensive reading in the literature review by the investigator (**Rand Corporation, 2013**).

Tool I: Bio-socio-demographic characteristics were included in two parts (**Appendix B**)

1st part: sociodemographic data : sex, age, marital status, education level, occupation, and residence

2nd part: Medical information include: past and present medical history, including medical diagnosis, smoking, medication

Tool II: A Short-Form health survey (SF-36) questionnaire arabic version adopted by **Ware and Sherbourne, (1992) & McHorney et al. (1994)** to measure the quality of life for patients with hepatitis C virus which include eight health domains: physical functioning (ten items from Q 3 to Q 12),

physical role problems (four items from Q 13 to Q 16) and due to emotional problems (three items from Q 17 to Q 19), energy or fatigue (four items: Q 23, 27, 29, 31), emotional wellbeing (five items Q 24- 26, Q 28, Q 30), social functioning (two items, Q 20, Q 32), Bodily Pain (two items, Q 21 & Q 22), and general health perceptions (five items: Q 1 and from Q33 to Q 36), which Q 2 refer to current patient health compared to one year ago.

Scoring system

Each subscale is scored from (0 to 100) when patient assessment indicates score 0 this means the worst score for quality of life but when have 100 mean they have the best score for quality of life. While the total scores were less than 50% considered as poor quality of life. If the total scores ranged from 50 % – 75% considered as good quality of life, and when the total scores were 75% or more considered as excellent quality of life.

Tool Validity and Reliability:

A panel of five experts in the field of medical surgicalnursing staff to examine validity of the content. No alterations of the content were be done allowing to the panel judgment on the clearness of sentences, suitability of the content, and categorization of items. Reliability was done by using the alpha Cronbach's test was .81 and it examined by many studies was 0.80 by **McHorney et al. (1994)**

Pilot Study :

Was conducted for 10 % (20 patients) of the total sample to test the study process and to evaluate the efficiency of tools.

Procedure:

The researcher met the patients during a time of outpatient clinics, introducing herself, and explained the purpose and nature of the study. oral consent was obtained to participate in this study. The researcher started a collection of data in 12 months by using Bio-socio-demographic characteristics for 15- 20 minutes for each patient. The researcher distributed the data collection sheets to respondents individually in the reception in the liver virology outpatient patient clinics at Minia university hospital and fever hospital. Collection of the study data was done on daily basis (2 to 3 days /week) during the morning shift. The researcher checked the completeness of each filled form after the participant filled it. Health-related quality of life was measured for every patient before and after 3 months from finishing the treatment.

Statistical data

Statistical analysis was done by using Statistical Package for the Social Science (SPSS IBM 25.0). Quality control was done at the stages of coding and data entry. Data were presented by using descriptive statistics in the form of frequencies and percentages for qualitative variables and mean & standard deviation (SD) for quantitative variables. Chi-square (χ^2) was used to test the association between two qualitative variables. T-test was used to measure mean differences of quality of life measured by short-form questionnaire (SF-36) between before and after treatment. Graphs were done for data visualization using Microsoft Excel. The P-value of ≤ 0.05 indicates a significant result while the P-value of > 0.05 indicates a non-significant result.

Results:

Table (1): Percentage distribution of Bio-socio-demographic characteristics of the studied Sample (n = 200)

Items	NO.	%
Age		
20- 30	34	17.0
31- 40	58	29.0
41 – 50	52	26.0
51 – 60	56	28.0
Mean ± SD	33.4 ± 8.1 years	
Sex		
Man	124	62.0
Woman	76	38.0
Marital Status		
Single	24	12.0
Married	160	80.0
Widow	16	8.0
Educational level		
Illiterate	28	14.0
Basic	38	19.0
Diplom	82	41.0
Bachelor	52	26.0
Residence		
Urban	32	16.0
Rural	168	84.0
Occupation		
Jobless	136	68.0
Work	64	32.0

Table (1): presents that 29.0% of the studied patient their age ranged between 31- 40 years with mean 33.4 ± 8.1 years, 62.0% of them was man. The highest percentage of the study sample were married and lived in rural areas constituted (80.0% & 84.0% respectively). Related to occupation status found that two-third (68.0%) of the study sample were jobless.

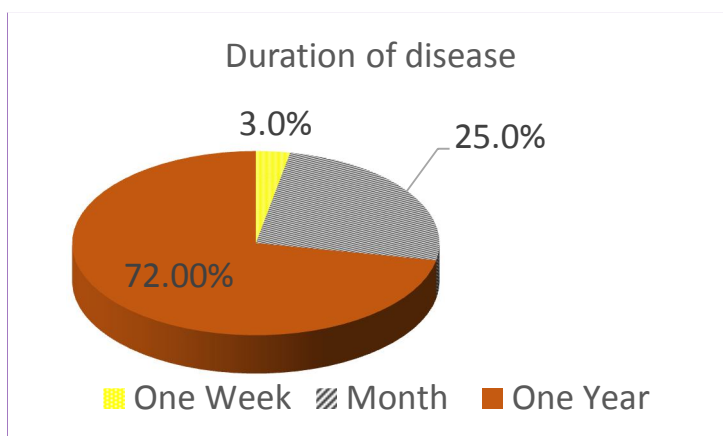


Figure (1): Percentage distribution of studied Sample regarding the duration of disease (n = 200)

Figure (1): illustrates that near to three quarters (72.0%) of the studied sample have duration of their disease from one year ago, while 25.0% of them from one month, and a minority of them from one week.

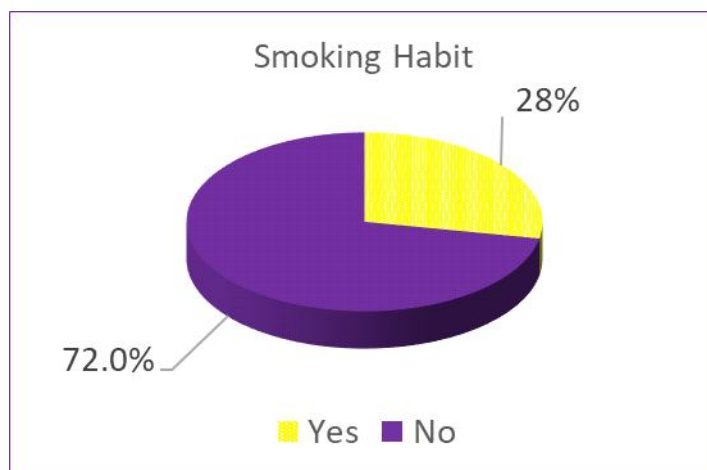


Figure (2): Percentage distribution of studied Sample regarding smoking habit (n = 200)

Figure (2): demonstrates that near to three quarters (72.0%) of the studied patient was not smokers and more than one-quarter (28.0%) of them was smoker.

Table (2): Mean scores of quality of life domain of the studied sample before and after 3 months from the administration of treatment

Quality of life domains	Before treatment	Three months after treatment	t-test	P-value
Physical functioning	47.1 ± 28.9	89.4 ± 12.7	13.401	.0001**
Role limitations due to physical health	42.8 ± 44.4	70.8 ± 41.4	4.609	.0001**
Role limitations due to emotional problems	57.0 ± 59.2	94.3 ± 55.3	4.609	.0001**
Energy	59.0 ± 30.7	77.6 ± 22.4	4.899	.0001**
Fatigue	44.7 ± 33.0	25.4 ± 28.2	4.446	.0001**
Emotional wellbeing	44.4 ± 25.4	64.7 ± 22.5	5.997	.0001**
Social functioning	53.5 ± 29.9	75.8 ± 25.7	5.647	.0001**
Pain	59.8 ± 35.5	81.2 ± 26.1	4.841	.0001**
General health	45.7 ± 19.2	58.4 ± 18.4	4.769	.0001**
Total SF-36	47.6 ± 24.9	75.6 ± 19.2	8.888	.0001**

Independent t test **Highly statistical significant difference at ≤ 0.01

Table (2): reveals that the total mean score of quality of life domain after 3 months of treatment with Sofosbuvir and Daclatasvir medication was higher than before treatment constitute (75.6 ± 19.2 & 47.6 ± 24.9) respectively with highly statistically significant (0.001).

Table (3) Relation between total Quality of life of the studied sample and their bio-socio-demographic characteristics before administration of Sofosbuvir and Daclatasvir (n= 200).

Bio-socio-demographic characteristics	Quality of life Before treatment							X ²	P-value
	NO.	Poor (n= 102)		Good (n= 66)		Excellent (n = 32)			
		No.	%	No.	%	No.	%		
Age/ Years									
20- 30	34	12	35.3	10	29.4	12	35.3	18.438	.005**
31- 40	58	40	69.0	8	13.8	10	17.2		
41 - 50	52	28	53.8	16	30.8	8	15.4		
51 - 60	56	22	39.3	32	57.1	2	3.6		
Gender									
Male	124	54	43.5	50	40.3	20	16.2	4.429	.109 NS
Female	76	48	63.2	16	21.0	12	15.8		
Marital Status									
Single	24	10	41.7	6	25.0	8	33.3	5.192	.268 NS
Married	160	80	50.0	56	35.0	24	15.0		
Widow	16	12	75.0	4	25.0	0	.0		
Educational level									
Illiterate	28	6	21.4	20	71.4	2	7.2	18.662	.005**
Basic	38	24	63.1	6	15.8	8	21.1		
Diplom	82	34	41.5	32	39.0	16	19.5		
Bachelor	52	38	73.1	8	15.4	6	11.5		
Residence									
Urban	32	18	56.3	4	25.0	3	18.7	.562	.755
Rural	168	84	50.0	29	34.5	13	15.5		
Occupation									
Jobless	136	70	51.5	20	29.4	13	19.1	17.957	.06 NS
Worker	6	6	100.	0	.0	0	.0		
Nursing	12	4	33.3	6	50.0	2	16.7		
Security	6	0	.0	6	100	0	.0		
Teacher	22	16	72.7	4	18.2	2	9.1		
Office worker	14	4	28.6	10	71.4	0	.0		
Driver	4	2	50.0	0	.0	2	50.0		

Chi-test for qualitative variables NS = not statistically significant differences ** Highly statistically significant differences

Table (3): shows that, 69.0% of studied patient who aged between 31- 40 years and 53.8% of the studied patient who aged between 41- 50 years had a poor total quality of life before administration of treatment with Sofosbuvir and Daclatasvir medication, and 73.1% of them who had bachelor degree and 63.1% of them who had basic education had poor quality of life before treatment with statistically significant differences (0.005 and 0.005) respectively.

Table (4): Relation between total Quality of life of the studied sample and their bio-socio-demographic characteristics 3 months after the administration of Sofosbuvir and Daclatasvir (n= 200).

Items	Quality of life 3 months after-treatment							X ²	P-value
	NO.	Poor (n= 26)		Good (n= 50)		Excellent (n = 124)			
		No.	%	No.	%	No.	%		
Age/ Years									
20- 30	17	2	1.0	6	3.0	26	13.0	7.522	.275 NS
31- 40	19	8	4.0	14	7.0	36	18.0		

Items	Quality of life 3 months after-treatment							X ²	P-value
	Poor (n= 26)		Good (n= 50)		Excellent (n = 124)				
	NO.	No.	%	No.	%	No.	%		
41 - 50	26	4	2.0	10	5.0	38	19.0		
51 - 60	28	12	6.0	20	10.0	24	12.0		
Gender									
Male	124	12	6.0	26	13.0	86	43.0	3.870	.144
Female	66	14	7.0	24	12.0	38	19.0		NS
Marital Status									
Single	24	2	1.0	8	4.0	14	7.0	1.737	.784
Married	160	20	10.0	38	19.0	102	51.0		NS
Widow	16	4	2.0	4	2.0	8	4.0		
Educational level									
Illiterate	28	4	2.0	14	7.0	10	5.0	11.277	.080
Basic	38	4	2.0	12	6.0	22	11.0		NS
Diplom	82	6	3.0	14	7.0	62	31.0		
Bachelor	52	12	6.0	10	5.0	30	15.0		
Residence									
Urban	32	8	4.0	10	5.0	14	7.0	3.431	.180
Rural	168	18	9.0	40	20.0	110	55.0		NS

Chi-test for qualitative variables NS = not statistically significant differences

Table (4): reveals that there were no statistically significant total Quality of life of the studied sample and their socio-demographic characteristics 3 months after the administration of treatment.

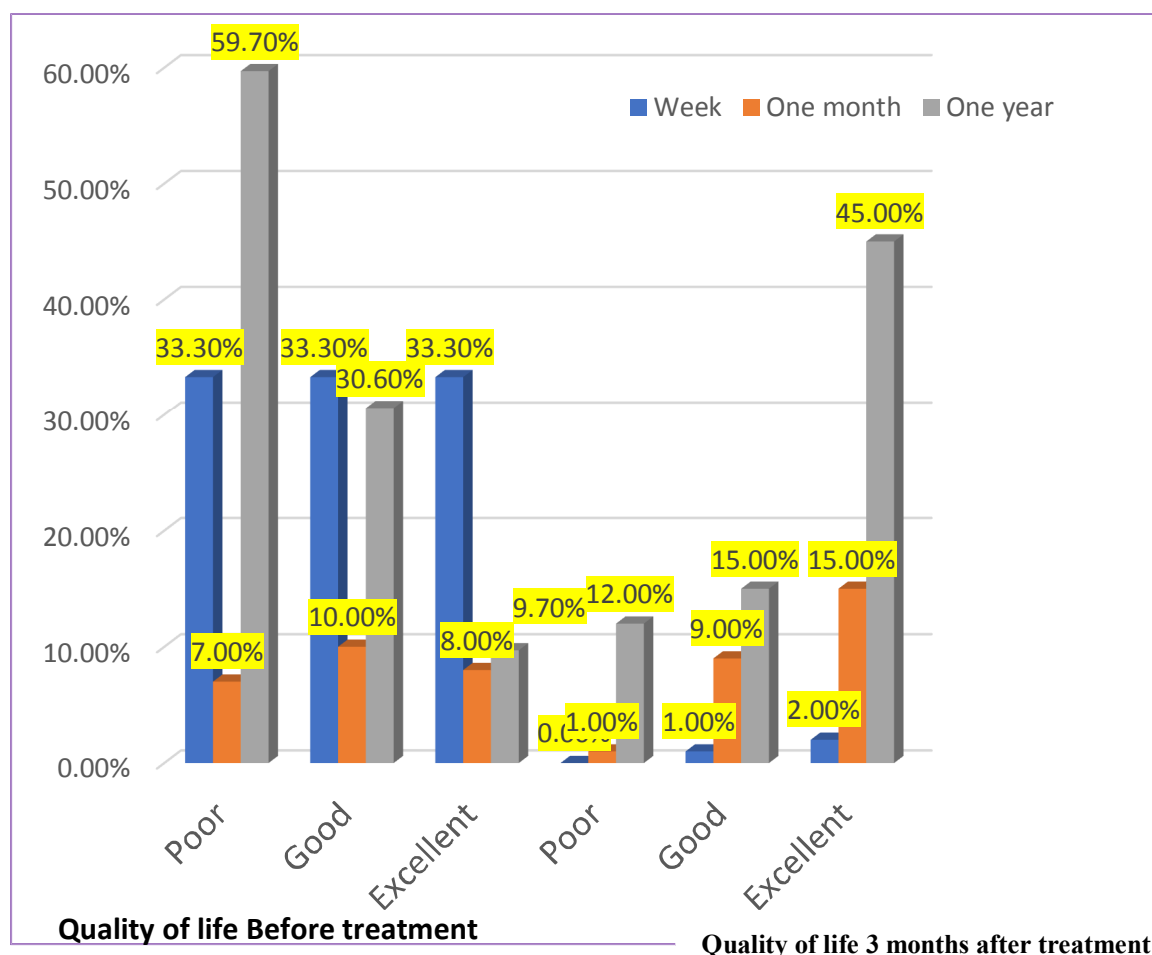


Figure (3): Comparison between total Quality of life of the studied sample and their duration of disease before and after 3 months administration of Sofosbuvir and Daclatasvir (n= 200).

Figure (3): illustrates that 59.7% of the studied patient with hepatitis from one year had poor quality of life before administration of treatment with Sofosbuvir and Daclatasvir medication decreased to 12.0% of them after 3 months of treatment

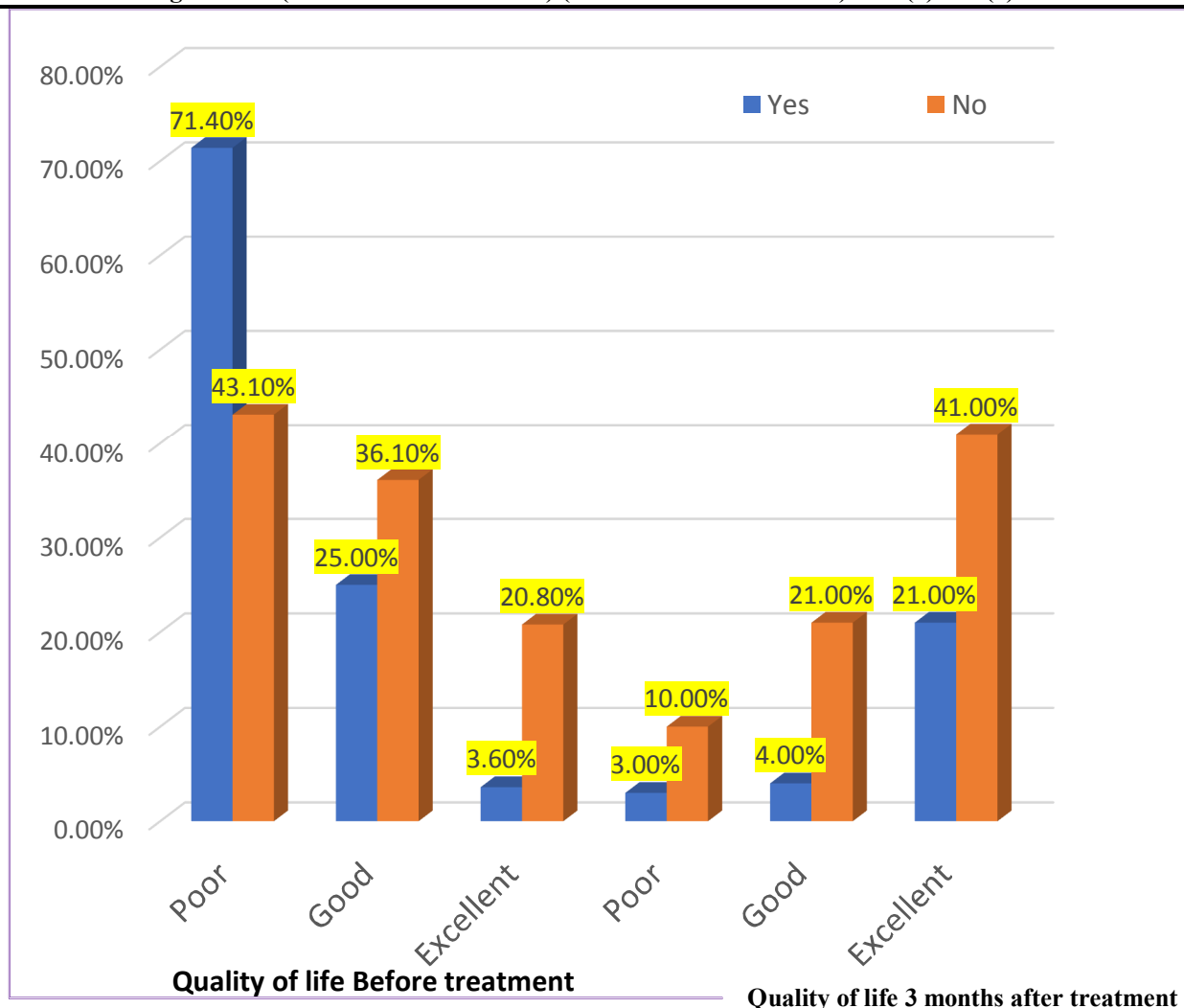


Figure (4): Comparison between total Quality of life of the studied sample and their smoking habits before and after 3 months administration of Sofosbuvir and Daclatasvir (n= 200).

Figure (4): illustrates that 71.4% of the smoker patient had poor quality of life before administration of treatment with Sofosbuvir and Daclatasvir medication decreased to 3.0% of them after 3 months of treatment

Table (5): Correlation between bio-socio-demographic characteristics and their total quality of life measured by short-form of health before and after 3 months of Sofosbuvir and Daclatasvir administration

Items	Quality of life before treatment		Quality of life 3 months after treatment	
	r	P - value	r	P - value
Age	.183	.068	-.201	.045
Educational level	.077	.449	.143	.155
Occupation	.025	.806	.113	.262
Duration of disease	-.329	.001**	.075	.459

Pearson and spearman correlation test**Correlation is significant at the 0.01 level

Table (5): reveals that there was a fair negative association between duration of disease of the studied sample with their total quality of life measured by short-form of health before administration of treatment with Sofosbuvir and Daclatasvir (r= -.329& P – value < .001).

Discussion

Infection with the hepatitis C virus (HCV) remains a major health problem, and the patients with hepatitis C virus necessitate to change their lifestyle and adopt healthy behaviors through an adjustment to a chronic medical condition, managing of symptoms and treatment health consequences, and making and maintain lifestyle changes (El-Maksoud et al., 2015).

Regarding the hepatitis patient characteristic, the present study showed their age mean 33.4 ± 8.1 years, less than two-third of them was male, the most of them was

married, about two-fifth of them had diploma degree and the most of them had lived in the rural area.

This result comes in the line with El Niwehy et al., (2018) reported that more than half of patients aged 51-60 years with (35.23±11.58) years; more than two-thirds were males; while the most of them were married and more than two-thirds were living in rural areas

As regarding education this result confirmed by Abdellatef & Mohamed (2019) reported that more than two-third of the studied group was living in rural areas.

This result goes in line with **Kandeel et al., (2017)** revealed that more than two-thirds of HCV patients were living in a rural areas. Also this result partially come in the line with **Faddan, Soliman, & Hassan, (2019)** reported that the majority of those patients were males, less than two-third of them were from rural areas, more than three quarters were with basic education and about two-third had low socioeconomic level.

Regarding the duration of disease, the present study illustrated that near to three quarters of the studied patient, the duration of their disease from one year ago, one-quarter of them from one month, and a minority of them from one week. This result differs from **(Zhang et al., 2020a)** who mentioned that more than half of the patients had disease duration greater than 5 years. Also, this result comes away from **Mapoure et al., (2018)** reported that the median duration of HCV infection was 32 months.

As related to the smoking habit, the current study demonstrated that less than three quarters of the studied patient was not smokers. This result contradicted with **Pericot-Valverde et al., (2020)** reported that the majority of the patients were current cigarette smokers. This difference due to more than one third of the studied patients was female and female in the upper Egypt the most female not smoke.

As regarding the mean scores of quality of life and its domain of the studied sample on before and after 3 months from administration of Sofosbuvir and Daclavir medication, the present study revealed that total mean score of quality of life domain after 3 months of treatment with Sofosbuvir and Daclavir medication were higher than before treatment constitute with highly statistically significant.

This result comes in the line with **Abd Elwahab Elsayed & Abd El-Aal (2017)** who mentioned that the quality of life of the patients was improved during the follow up phase than baseline before initiated the course of treatment and during the treatment regimen. Also, these results came in accordance with **Youssef et al., (2017)** found a significant change in HRQL across the three different periods among patients receiving DAAs before, during and at the end of therapy. Moreover, **Younossi et al., (2016)** found that HRQL improvement was progressive overtime after the end of treatment, with scores after 24 weeks greater than at 12 weeks.

Concerning the comparison between the studied sample regarding their total quality of life levels before and 3 months after the administration of Sofosbuvir and Daclavir medication, the present study showed that there was improvement in total quality of life this appear through more than half of hepatitis patients were poor in quality of life before treatment with Sofosbuvir and Daclavir medication become about two-thirds of them become excellent in quality of life after 3 months from treatment with highly statistically significant differences.

This result confirmed with **Younossi & Henry, (2015)** revealed that interferon-free regimens containing sofosbuvir and ledipasvir have minimal negative effects on health-related quality of life during treatment. Also, **Younossi et al., (2016)** found that patients who achieved a sustained virologic response at 12 weeks after treatment reported significant improvement in their outcomes in interferon-free regimens. These results due to the patient received accurate dose of medication follow physician order, and they feel satisfaction toward medication action.

As related the relation between total Quality of life of the studied sample and their bio-scio-demographic

characteristics before administration of Sofosbuvir and Daclavir treatment, the current study showed more than two-third of studied patient who aged between 31- 40 years and more than half of the studied patient who aged between 41- 50 years had poor total quality of life before administration of treatment with Sofosbuvir and Daclavir medication, and about three-quarter of them who had bachelor degree and near two-thirds of them who had basic education had poor quality of life before treatment with statistically significant differences. Also, more than of the studied patient with hepatitis from one year had poor quality of life before administration of treatment with Sofosbuvir and Daclavir medication and more than two thirds of the studied smoking patient had poor quality of life before administration of treatment with a statistical significance.

These results agree with **Pereira & Fialho, (2016)** reported that there was a statistical significant association between patient age and their quality of life. Also, this result was confirmed by **Skevington, (2012)** reported there astatically differences between patient age and quality of life.

This result comes in accordance with **Zhang et al., (2020b)** who studied " Health-Related Quality of Life among Patients with Hepatitis C Virus Infection: A Cross-Sectional Study in Jianping County of Liaoning Province, China " and mentioned that there were statistical significant differences between the quality of life of a patient with HCV and the disease years. This difference may be due studied patients not administered any therapeutic management for their disease so their quality of life was poor.

This result comes in accordance with **Lynch et al., (2018)** reported that smoking had a significantly larger association with moderate/severe pain (adjusted odds ratio [or]=1.50, $p < 0.001$) than among veterans without HCV (adjusted or=1.26, $p < 0.001$).

Concerning the relation between total Quality of life of the studied sample and their bio-scio-demographic characteristics 3 months after administration of Sofosbuvir and Daclavir medication, the present study revealed that there were no statistically significant total Quality of life of the studied sample and their bio-socio-demographic characteristics 3 months after administration of treatment. This result was come in the line with **Kang et al., (2005)** reported that there was statistical significance difference between demographic characteristics and quality of life after treatment with antiviral medication. These results may be due to the effective treatment with Sofosbuvir and Daclavir.

Regarding the correlation between demographic characteristics and their short-form of health before and after 3 months of administration of Sofosbuvir and Daclavir medication, the current study revealed that there was a fair negative association between duration of disease of the studied sample with their total quality of life measured by short-form of health before administration of treatment with Sofosbuvir and Daclavir. This may be due to the length of the disease affect the deterioration of the patient's status that affects the outcome of the treatment and adversely affect the patient's quality of life.

Conclusion

Based on the results of the present study, it can be concluded that:

Total mean score of quality of life domain after 3 months of treatment with Sofosbuvir and Daclatasvir

medication was higher than before treatment constitutes highly statistically significant.

Besides, there was a fair negative association between duration of disease of the studied sample with their total quality of life measured by short-form of health before administration of treatment with Sofosbuvir and Daclatasvir so the administration of Sofosbuvir and Daclatasvir for patients with virus C, had a positive influence on their life, especially for newly diagnosed patients.

Recommendations

Based on the results of the present study and research questions the following recommendations are suggested:

1. Early screening for hepatitis C to begin early suitable treatment and minimize the effect of disease on their quality of life
2. Provide safety precaution guide before start Sofosbuvir and Daclatasvir combination therapy through health education session and simple arabic brochures at outpatient clinics and hepatic centers which provide healthy life style measures regarding nutrition, physical activity, personal hygiene, drug administration.
3. Increase patients awareness regarding adverse reaction of Sofosbuvir and Daclatasvir combination therapy through health education classes provided by health care team specially the nurses and encourages the patient to change their life style.
4. Further studies about factors enhancing quality of life among hepatitis C virus patients undergoing Sofosbuvir treatment is needed.

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