The Effect of Interferon Therapy among Hepatitis C Patients on their Quality of Life, Egypt

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Abstract: Background: Hepatitis C virus (HCV) is the major cause of liver disease in many countries worldwide. The health-related quality of life (HRQoL) of patients with chronic liver disease has been shown to be impaired in numerous studies. The factors which influence HRQoL in treated HCV patients, are not yet quite clear. The insight that HCV impairs HRQoL is a necessary first step to understand why it is important to measure HRQoL in clinical practice and know how to use this information throughout the HCV antiviral therapy. This study aimed to assess the impact of interferon treatment of HCV patients on their HRQoL by an experimental case-control study among 120 HCV patients on interferon treatment and 120 HCV patients were not on antiviral therapy, attending outpatient clinics of interferon center National Medical Institute of Damanhour, Lower Egypt. Data were collected via questionnaires included the patient's socio-demographic characteristics and bio-medical history about hepatitis C virus infection. An Arabic version of a short form of chronic liver questionnaire CCLDQ which was designed to measure HRQoL secondary to liver disease was used to assess patients' HRQoL scores. The results showed that the majority of the treatment patients were with high level of HRQoL for all of the studied health domains, and the majority of control patients were with moderate level of HRQoL in five out of the six studied health domains and with high HRQoL for the domain of tiredness. There was a significant gender difference in the favor of females for the domains of tiredness, abdominal signs, and anxiety and general symptoms for the study group patients. Study group patients with family history of HCV infection showed significant differences for the health-domains of tiredness, role emotional, abdominal signs, physical activity, (P=0.000) and general symptoms, (P =0.001). In contrast to control group patients, study group patients with bad liver conditions scored higher mean ± SD values of HRQoL for the domains of role emotional, (P =0.044), abdominal signs, (P =0.000), and anxiety (P =0.001), compared their counterparts with good liver conditions of the group. Conclusion: The majority of the study group patients were with high level of HRQoL scores for all studied health domains. While the control group patients were with moderate level of HRQoL scores for five out of the six health-domains and were had high level only for the health-domain of tiredness. There was significant gender difference in four out of the six health domains in the favor of females. Patients on treatment and with family history of the disease earned better score in five out of the six studied domains in contrast to control group. Patients on treatment with bad liver conditions scored higher means ±SD values HRQoL with significant difference for health domains of role emotional, abdominal signs and anxiety.
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The increasing prevalence of chronic disease in developed countries has led to an increased focus on the emotional and social well-being of patients as well as their physical well-being referred to as HRQoL. However, using HRQoL for the, improvement of physician consultations is increasingly being acknowledged.[14] The effect of HCV on quality of life (QoL) in chronically infected patients has been the subject of such studies.[17] Studies in different populations showed different results, in Japan, no characteristic subjective symptoms were found in patients with HCV compared to healthy controls.[18 ,19] The prevalence of hepatitis C ,in Pakistan, has been estimated as high as 35% in some areas.[20,21] The HCV infection is almost a major public health problem worldwide with a prevalence ranging from 0.5% to 20% in highly endemic countries.[22] Although the disease has been thought to be asymptomatic, it is now

1. Introduction:

Chronic hepatitis C virus (CHCV) infection is a prevalent and expensive condition affecting millions of people.[1] Hepatitis C virus (HCV) leads to cirrhosis in up to 20% of those chronically infected,[2] and is the primary indication for liver transplantation worldwide.[3] The economic burden of the disease is multiplied by dramatic impact of HCV on health-related quality of life (HRQoL). This is resulted from complications of advanced liver diseases, such as encephalopathy, variceal haemorrhage, ascites and liver transplantation.[4,5] Despite of this consensus the majority of patients has asymptomatic seropositivity,[6] indicating that HCV itself may diminishes HRQoL in the absence of advanced liver disease.[7-14] chronic infection with the HCV has a profound effect on HRQoL, with fatigue, depression, and neurocognitive deficits among the most common complains.[15]

teaching and learning to promote positive health actions to facilitate behavior change.

Aim of the Study

This study aimed to:

Assess the impact of interferon treatment on the health-related quality of life of patients with chronic hepatitis C virus infection.

Research question:-

Did the interferon treatment improve the quality of life of patients with chronic hepatitis C virus?

2. Subjects and Method

The study design:

This study is descriptive a case – control study.

Target population and settings:

The study subjects were hepatitis C virus patients, receiving interferon therapy and attending the Interferon Center of Damanhur Medical National Institute at El Behaira governorate.

Study population and sampling:

The study conducted from 1st of July, 2010 to 1st of August for a period of one month .

Sampling: The study sample was randomly selected, all of participants received a full explanation of the objectives of the study before accepting to participate in this work. Two hundred and seventy (270) were interviewed, twenty (20) were interviewed for a pilot study, and ten (10) of the total were excluded, and the remaining two hundred and forty (240), chronic HCV confirmed infection individuals. The subjects were divided into two groups, (n=120) patients who entered INF-treatment (study group). While the other, (n=120) hepatitis C patients, who were excluded from INF-treatment, considered as (control group) subjects.

Medical ethics: manger of the center was requested to give permission to recruit patients. During data collection, a written consent was obtained from individual patient after been told that their participation is completely voluntary in nature, and that they could discontinue at any time. Confidentiality was secured, as no names. They were also informed they have the right to skip any questions that make them uncomfortable.

Methods: Data collection:

A pilot study was conducted among 20 HCV patients receiving interferon to test the designed questionnaire, consequently some questions were cancelled and some others were re-formed. Those participated in the pilot study were excluded. In the baseline interview, the re-formed questionnaire was answered by direct interview with patient. The questionnaire took about 15 to 30 minutes to be filled. Questionnaire sheets to collect the following data, it consists of two tools:-

Tool 1- Socio-demographic data: age, residence, education, occupation, gender, marital status, number

understood that it can significantly compromise patient HRQoL.[7,23,24]

The effects of hepatitis C virus infection on QoL are emerging as important parameters in the evaluation of patients. Physicians have the perception that patients with HCV are largely asymptomatic and that the disease seldom has an impact on patients' lives.[25] However, studies with large numbers of patients showed that hepatitis C has a negative impact on QoL, which may help justify therapy in patients with less advanced histological disease.[23-25]

Hepatitis C viral infection in Egypt was estimated in 1996, to be approximately 15% of the Egyptian population, and more than five million Egyptians were chronically infected with HCV.[26] The high prevalence of the disease in Egypt has recently been estimated to be, 10 to 20%,[27] and shown to be higher in lower Egypt than upper Egypt. Higher rate of prevalence was also found in rural areas than urban compounds.[28] This situation of HCV infection in Egypt referred to the use of contaminated syringes' needles during previous schistosomiasis treatment campaigns.[29] The other factors of high prevalence of HCV infection are blood transfusion, dental treatments, and sharing syringe needles among drug addicts.[29-31]

Although most chronic HCV patients have few or no symptoms during the early stages of their illness, several studies have reported impairment in HRQoL compared to healthy individuals.[24,32,33] Most studies have used an instrument based on the SF-36.[23,24,32] However, the development of the Chronic Liver Disease Questionnaire (CLDQ) enabled to evaluate and assess various indices related to the QoL in these patients, including emotional changes, fatigue, physical activity, anxiety, worry and abdominal symptoms. It is likely to become more sensitive to changes in QoL,[34] and it has moderate test/retest reliability.[35, 36]

The HRQoL is often defined as the impact of a disease and/or treatment on a patient's physical emotional and social functioning.[37] Regarding HCV patient HRQoL, was found to be strongly related to interferon (INF) therapy,[38] Treatment further diminishes HRQoL of the patients due to INF side effects.[24,39] During antiviral treatment the HRQoL is further compromised and deteriorated,[7,23-25] and therapy impairs HRQoL most substantially in those patients with anemia.[40] Several studies have reported a reduction in the health-domain of fatigue after treatment of HCV as a result of interferon-based treatment.[23,24,41] During the initial two weeks of INF therapy, the decline of HRQoL scores was noticed for the health domain of role physical components.[40]

Community health nurses are actively involved in identifying the risk factors for infection in population in the event of epidemic. They apply the principles of

treatment and 60% males versus 40%females of the control), no significant difference was observed between the two sexes, (χ^2=2.4, *P* =0.19).Nearly half (45.8%) of the patients on treatment were illiterate, while most of the control subjects could read & write and secondary school levels, (38.3% and 33.3%, respectively), with significant difference, (χ^2=16.2, *P* =0.001), between the two groups of patients. Noticeably, married participants contributed the majority of the two compared groups,(85.0%)for interferon group and(98.3%) for the control group. There was a significant statistically difference, (t=13.9, *P* =0.000), concerning marital status of the two studied groups.

Farmers contributed the highest percentages among the study sample (36.7%for on treatment and 30%for control), no significant difference was observed, (χ^2= 8.3, *P* =0.08). Patients on interferon, having more than three children, accounted (48%), versus (33.7%) of the control patients. While patients who on treatment and had less than three children, accounted (46%), versus (66.1%) of the control patients. There was a significant difference, (χ^2= 13.5, *P* =0.001).

The table shows that three quarters (75%) of the patients on interferon and more than half, (58.3%) of the control subjects were rural residents, with significant difference, (χ^2= 7.5, *P* =0.000), between the two studied groups. About two-thirds (65.8%) of the subjects on interferon group had no sufficient income. On the other hand, about 60% of the control patients were with sufficient income. There was a significant difference, (χ^2= 15.1, *P* =0.000) between the two studied groups, concerning income status.

Table (2): Shows the biomedical data of the patients on interferon treatment and patients of control group. The results showed that, (62.5%) of the patients on treatment had infection 1 to 3 years previous to the study and (36.7%) of this group had the disease 3-6 years. On the other side 40% of the control group had the disease 3-6 years of period. The difference between the two studied groups was significant, (χ^2= 36.6, *P* =0.000). It was noticed that more than half of the two groups were not admitted to hospital before the study , (57.5% for patients on treatment and 51.7% for the control). No significant difference was detected, (χ^2= 0.82, *P* =0.364). The majority patients of groups, (65% and 73.3%), had efficient liver conditions, with no significant differences, (χ^2= 1.9, *P* =0.162).It was observed that more than half, (53.3%) of the patients on interferon treatment had no family history of the disease.

Table (3): Showed that the percentage of levels of the studied quality of life (QoL) health domains, namely, tiredness, role emotional, abdominal signs,

of children, duration of infection, admission to hospital, family history, family income, liver condition.

Tool II - Measuring the Quality of life (QOL) Chronic Liver Disease Questionnaire (CLDQ) was used as HRQoL assessment instrument. This instrument was developed specially for liver disease.[34] The CLDQ includes 29-items in the following health-domains, fatigue, role emotional, abdominal symptom, systemic symptoms physical activity and worry. It has 7-likert scale type of answers ranging from "all of time" to "non of the time", with possible range from worst to best QoL.[34] The construct validity of the CLDQ was supported by a strong correlation with patients global rating scores, (r=0.84; *P* =0.02).[34,43] This allowed CLDQ wide application in hematology research.[44] The original version of CLDQ was translated into Arabic version, with 5-likert scale type of answers, the health-domains were namely, tiredness with 5-items, role emotional with 8-items, abdominal signs with 3-items, anxiety with 4-items, physical activity with 3-items and general symptoms with 5-items. Each question in the questionnaire was answered in 3 forms, yes poor (0), only littlie (1point), and not at all or well (2 points). The sum of scores was calculated individually for each set of the 6 domains in the QOL scales, as well as for the total scale to calculate the general QOL. The QOL total score ranged from 0 point, minimum to a maximum of 36 points.

The QOL score was divided into:-
Low score (poor): ≤50%of the total scores,- Moderate score: ≥50%-75% of the total scores, High score (good): if the sum was ≥75 % of the total scores.

Statistical analysis:
The results were analyzed using SPSS software version 17.0. The *P* -value < 0.05 was taken as a cutoff for statistical significance. The chi-square test (χ2) and Fisher exact tests were used for comparison among proportions for qualitative data. Both of the t-test and ANOVA F-test were used to compare among two and more than two groups respectively; for numerical data, quantitative data using their means and standard deviations.

3.Result:
Table (1) shows the socio-demographic characteristics of HCV patients on interferon treatment and HCV patients without treatment (control group). The socio-demographic characteristics showed that, the age group 31-40 years of the patients on interferon accounted, (40%) whereas, the control group patients percentage of age group 51 years and above, increased to more than half, (56.7%). There was a significant difference, (χ^2= 90.9, *P* =0.000), between the two groups. As regards to gender(60% for both sexes on

patients had higher means ± SD of all studied health domains compared to other jobs, with significant differences for, abdominal signs, (F=5.5, P =0.000), and general symptoms, (F=2.9, P =0.022).

On the other hand, having more than three children, showed higher means ± SD, with significant difference for the health domain of physical activity, (F=3.4, P =0.035). Similarly, residents of rural areas of this studied patients had higher means ± SD values than their counterparts of urban areas, for all the domains with significant differences, for tiredness, (t=2.5, P =0.14), and role emotional, (t=2.4, P =0.17). The family income status of patients on treatment, showed that, who with sufficient income, reported higher means ± SD values with significant differences for 5 of 6 studied domains, namely, role emotional, (t=2.3, P =0.024), abdominal signs, (t=3.5, P =0.001), anxiety, (t=4.3, P =0.000), physical activity, (t=2.4, P =0.018), and general symptoms,. (t=2.5, p =0.015).

Tables (5): Illustrates the mean ± SD of the selected health domains of HRQoL of HCV control patients , according to their socio-demographic characteristics. Variations were observed among mean ± SD scores of age groups of control group showed significant differences, for the health domains of , role emotional, (F=10.1, P =0.000), physical activity, (F=4.6, P =0.004), and general symptoms, (F=2.7, P =0.044). Regarding gender effect on the QoL of control patients, significant differences between the two sexes, were reported for the health domains of role emotional, abdominal signs, anxiety,(t=2.1, P=0.035 , t=2.9, P =0.004, t=2.1, P =0.035 respectively).

Concerning the educational levels of control group, significant differences were found for the health domains of tiredness, (F=6.9, P = 0.000), role emotional, (F=3.5, P =0.016), physical activity, (F=3.0, P =0.030), and general symptoms, (F=7.0, P =0.000).Regarding the marital status , significant differences between the single and married patients were reported for the health domains of role emotional, (t=2.7, P =0.007), and physical activity, (t=2.3, P =0.02)respectively.

Regarding the job status of control patients, significant differences were noticed between different careers for health domains of role emotional, (F=3.4, P = 0.010), abdominal signs, (F=4.1, P =0.003), physical activity, (F=4.40, P =0.002), and general symptoms, (F=5.6, P =0.000). Concerning number of children, all patients of control group had children. It was observed that those patients having less than three children or more affected significantly the health domains of role emotional and physical activity, (F=3.3, P = 0.001, and F=2.5, P =0.013, respectively). On the other hand, the health domain of role emotional of rural patients decreased significantly, (t=3.4, P =0.001), while the opposite effect was the case for the health domains of

anxiety, physical activity, and general symptoms. In addition, to the overall health, for the both groups, it was noticed that the QoL health domain of tiredness accounted 85% of patients on interferon and 68.3% of the control subjects. There was a significant difference, (χ^2= 9.3, P =0.002). The health domain of role emotional was high (81.7%) of the treatment subjects, while it was moderate for, (93.3%) of the control group. A significant different was detected, (χ^2= 95.1, P =0.000) between the two compared groups of patients.

As regards to the abdominal signs, similar trend was observed between the two studied groups, where moderate and high levels of abdominal signs were reported, (45.8% and 49.2%, respectively) for on treatment group and (63.3% and 35%, respectively), for the control. There was a significant difference of (χ^2=8.2, P =0.016). More than half (52.5%) who on treatment had high anxiety conditions compared to, (88.3%) of the control had moderate anxiety conditions, significant difference was found, (χ^2= 45.9, P =0.000). Concerning the health domain of physical health, (82.5%) on treatment patients had high level of physical activity. Two-thirds, (66.7%) of the control patients had moderate physical activity. There was a significant difference of (χ^2= 59.5, P =0.000).While, (80.8%) patients on treatment had general symptoms, compared to,(61.7%) of the control subjects who had moderate level of the same health domain, with significance of (χ^2= 45, P =0.000). It was noticed that more than three-quarters, (77.5%) of the on interferon had high overall health status, where nearly similar proportion, (76.7%) of the control subjects were with moderate overall health status, with significant of (χ^2= 70.4, P =0.000).

Table (4): Shows the mean ± SD of selected health domains of HRQoL for HCV patients on interferon treatment, according to their socio-demographic variables. It was noticed that the age group of 51years and above had the highest means ± SD of the studied health domains of the HRQoL Significant differences in health domains for age groups were reported for, tiredness (F=2.9, P =0.035), role emotional, (F=4.8, P =0.003), and anxiety, (F=6.4, P =0.000). Similarly, females possessed higher means ± SD of all the studied health domains, with statistical differences observed for, tiredness (t=2.2, P = 0.029), abdominal signs, (t=2.6, P =0.009), anxiety, (t=1.9, P =0.05) and general symptoms, (t=2.3, P =0.021).

Regarding educational level, no significant differences were detected among the different levels of education of this group of patients for all studied health domains. As well, the similar observation was reported for the marital status of this group. Regarding the job status of this group, it was noticed that retired

those who had inefficient livers showed, significant difference for the health domains of role emotional, abdominal signs and anxiety, (t=2.10, P =0.044, t=4.2, P =0.000, and t=3.1, P =0.003, respectively), compared to patients who had efficient livers.

Tables (7): Illustrates the means ± SD of the health related quality of life (HRQoL), selected domains of HCV control group patients, according to their biomedical data. Comparing disease duration effect on the quality of life of this group, it was observed that subjects who had the infection more than 6 years had highest means for the health domain of tiredness, differing significantly from other disease durations, (F= 10.4, P =0.000). Also significant differences were detected for the health domains of physical activity and general symptoms, (F=6.6, P =0.002, and F=26.7, P =0.000, respectively). No significant differences were observed for the rest of disease durations.

physical activity and general symptoms, (t=3.3, P =0.001, and t=4.5, P =0.000, respectively). As regards to monetary status of patients , significant difference was detected for the domain of abdominal signs, (t=2.1, P =0.038).

Table (6): Shows the mean ± SD of the selected health domains of QoL of HCV patients on interferon treatment, according to their biomedical data. Regarding the days of disease, no significant differences were found, except for the health domain of physical activity, (F=4.3, P =0.016). For hospital admission, no significant differences were observed for all studied health domains, between hospitalized and non-hospital patients.

As regards to family history of the disease, patients who had family history of the disease showed, significant differences for health domains of tiredness (t=1.9, P =0.05), role emotional, (t= 2.3, P =0.026), and general symptoms, (t=2.1, P =0.043). Concerning liver conditions of who on treatment , the patients

Table (1): Distribution of the HCV patients on interferon therapy and control HCV patients, according to their socio-demographic characteristics

Socio demographic data	Study Groups				X^2	P
	Interferon		Control			
	No	%	No	%		
Age						
▪ 20 - 30	24	20.0	0	0.0	90.9	0.000*
▪ 31 - 40	48	40.0	8	6.7		
▪ 41 - 50	35	29.2	44	36.7		
▪ 51 +	13	10.8	68	56.6		
Gender						
▪ Male	60	50.0	72	60.0	2.4	0.119
▪ Female	60	50.0	48	40.0		
Educational level						
▪ Illiterate	55	45.9	28	23.3	16.2	0.001*
▪ Read & write	30	25.0	46	38.4		
▪ Secondary	34	28.3	40	33.3		
▪ University	1	0.8	6	5.0		
Marital status						
▪ Single	18	15.0	2	1.7	13.9	0.000*
▪ Married	102	85.0	118	98.3		
Job status						
▪ Worker	23	19.2	20	16.7	8.3	0.080
▪ Employee	11	9. 2	24	20.0		
▪ Farmer	44	36.6	36	30.0		
▪ Retired	2	1.7	6	5.0		
▪ Housewife	40	33.3	34	28.3		
Number of Children						
▪ No children	6	5.9	0	0.0	13.5	0.001*^
▪ >3	49	48.0	40	33.9		
▪ <3	47	46.1	78	66.1		
Residence						
▪ Rural	90	75.0	70	58.3	7.5	0.006*
▪ Urban	30	25.0	50	41.7		
Income						
▪ Sufficient	41	34.2	71	59.2	15.1	0.000*
▪ Not Sufficient	79	65.8	49	40.8		

^ P value based on Mont Carlo exact probability X^2 = chi-square values; * P < 0.05 (significant)

Table (2): The Medical records of the HCV Patients on interferon therapy and control HCV- patients

Biomedical data	Group				X^2	P
	Interferon		Control			
	No	%	No	%		
Disease period						
▪ <3 years	75	62.5	42	35.0	36.6	0.000*
▪ 3-6	44	36.7	48	40.0		
▪ >6	1	0.8	30	25.0		
Hospital admission						
▪ Yes	51	42.5	58	48.3	0.82	0.364
▪ No	69	57.5	62	51.7		
Liver's condition						
▪ Efficient	78	65.0	88	73.3	1.9	0.162
▪ Inefficient	42	35.0	32	26.7		
Family history						
▪ Yes	56	46.7	64	53.3	1.1	0.302
▪ No	64	53.3	56	46.7		

* $P < 0.05$ (significant); X^2 = chi-square values

Table (3): Distribution of grades selected Health-domains of Quality of Life of the Studied Subjects

QOL domains	Studied Groups				X^2	P
	On Interferon therapy		Control			
	N	%	N	%		
Tiredness						
▪ Moderate	18	15.0	38	31.7	9.3	0.002*
▪ High	102	85.0	82	68.3		
Role- emotional						
▪ Moderate	22	18.3	112	93.3	95.1	0.000*
▪ High	98	81.7	8	6.7		
Abdominal signs						
▪ Low	6	5.0	2	1.7	8.2	0.016*
▪ Moderate	55	45.8	76	63.3		
▪ High	59	49.2	42	35.0		
Anxiety						
▪ Moderate	57	47.5	106	88.3	45.9	0.000*
▪ High	63	52.5	14	11.7		
Physical activity						
▪ Moderate	21	17.5	80	66.7	59.5	0.000*
▪ High	99	82.5	40	33.3		
General symptoms						
▪ Moderate	23	19.2	74	61.7	45.0	0.000*
▪ High	97	80.8	46	38.3		
Overall Health						
▪ Moderate	27	22.5	92	76.7	70.4	0.000*
▪ High	93	77.5	28	23.3		

* $P < 0.05$ (significant)
X^2 = chi-square values

Table (4): Distribution of the mean and standard deviation of HRQOL of HCV patients on interferon therapy, according to their socio-demographic characteristics.

Socio demographic characteristics	Tiredness (1-25)		Emotional		Abdominal signs		Anxiety		Physical activity		General symptoms	
	Mean	±SD	Mean	±SD	Mean	±SD	Mean	±SD	Mean	±SD	Mean	±SD
Age												
▪ 20 - 30	20.5	2.7	29.0	4.8	9.5	3.0	13.0	2.9	12.0	2.1	19.1	3.3
▪ 31 - 40	19.6	3.7	31.9	6.1	10.0	3.0	13.3	3.8	12.8	2.0	19.6	4.3
▪ 41 - 50	21.1	3.6	32.7	5.6	10.7	2.9	14.5	3.6	12.4	2.8	20.3	4.2
▪ 51 +	22.8	4.3	36.2	4.9	11.8	1.4	17.6	1.9	13.8	2.0	22.1	4.6
F (P)	2.9 (0.035)*		4.8 (0.003)*		2.4 (0.070)		6.4 (0.000)*		1.8 (0.148)		1.7 (0.169)	
Gender												
▪ Male	19.9	3.9	31.6	5.8	9.6	3.2	13.4	3.7	12.6	2.5	19.1	4.4
▪ Female	21.3	3.2	32.5	6.0	11.0	2.4	14.7	3.5	12.7	2.2	20.8	3.7
t (P)	2.2 (0.029)*		0.87 (0.836)		2.6 (0.009)*		1.9 (0.050)*		0.43 (0.671)		2.3 (0.021)*	
Education level												
▪ Illiterate	21.4	3.5	32.8	5.8	10.7	3.1	14.5	3.6	12.9	2.3	20.7	3.9
▪ Read & write	19.6	3.7	30.9	4.7	10.1	3.3	13.3	3.8	12.6	2.1	18.4	4.2
▪ Secondary	20.0	3.7	31.5	6.8	9.6	1.8	13.9	3.5	12.1	2.5	20.0	4.2
▪ University	25.0	0.0	40.0	0.0	15.0	0.0	20.0	0.0	15.0	0.0	25.0	0.0
F (P)	2.5 (0.064)		1.4 (0.253)		1.9 (0.128)		1.7 (0.168)		1.1 (0.360)		2.5 (0.067)	
Marital status												
▪ Single	20.8	3.7	32.1	4.8	9.5	3.7	14.2	3.2	13.0	1.6	19.2	4.3
▪ Married	20.5	3.7	32.0	6.0	10.4	2.7	14.1	3.7	12.6	2.5	20.1	4.1
t (P)	0.32 (0.746)		0.06 (0.952)		1.3 (0.206)		0.11 (0.917)		0.70 (0.485)		0.81 (0.422)	
Job status												
▪ Worker	20.0	3.9	33.3	4.0	8.2	3.2	13.9	3.9	13.0	1.7	19.0	4.2
▪ Employee	19.8	3.4	29.1	5.9	10.4	1.7	13.2	4.2	11.8	3.2	17.0	4.6
▪ Farmer	20.2	4.0	31.1	5.8	10.5	3.0	13.7	3.1	12.8	2.3	20.2	4.0
▪ Retired	23.0	2.8	34.0	8.5	14.0	1.4	18.5	2.1	15.0	0.0	25.0	0.0
▪ House wife	21.4	3.2	33.0	6.5	11.1	2.2	14.7	3.8	12.4	2.4	20.7	3.8
F (P)	1.1 (0.381)		1.6 (0.176)		5.5 (0.000)*		1.4 (0.247)		1.2 (0.314)		2.9 (0.022)*	
number of children												
▪ No children	19.6	4.0	30.5	6.2	9.3	3.7	13.6	3.1	12.0	2.6	18.3	4.8
▪ >3	20.9	3.3	33.3	5.4	10.7	2.7	14.2	3.6	13.3	2.1	20.6	3.9
▪ <3	20.7	3.8	31.5	6.0	10.4	2.6	14.2	4.0	12.3	2.4	20.1	3.9
F (P)	1.1 (0.322)		2.2 (0.119)		1.9 (0.154)		0.28 (0.753)		3.4 (0.035)*		2.6 (0.081)	
Residence												
▪ Rural	21.0	3.5	32.8	5.3	10.4	3.2	14.1	3.5	12.8	2.2	20.3	3.8
▪ Urban	19.2	3.9	29.8	6.9	10.1	2.0	13.9	4.0	12.3	2.7	18.8	5.0
t (P)	2.5 (0.014)*		2.4 (0.017)*		0.43 (0.665)		0.32 (0.752)		0.83 (0.414)		1.6 (0.121)	
Family income												
▪ Sufficient	20.6	4.1	33.7	5.9	11.5	2.6	15.9	3.0	13.3	2.4	21.2	4.4
▪ Not sufficient	20.5	3.4	31.2	5.7	9.7	2.9	13.1	3.6	12.3	2.2	19.3	3.9
t (P)	0.13 (0.899)		2.3 (0.024)*		3.5 (0.001)*		4.3 (0.000)*		2.4 (0.018)*		2.5 (0.015)*	

F: One way ANOVA

T: Independent samples t test

* $P < 0.05$ (significant)

Table (5): Distribution of the Mean and Standard Deviation of HRQoL of HCV control group patients, according to their Socio-demographic characteristics.

Socio demographic data controls	Tiredness		Emotional		Abdominal signs		Anxiety		Physical activity		General symptoms	
	Mean	±SD	Mean	±SD	Mean	±SD	Mean	±SD	Mean	±SD	Mean	±SD
Age												
▪ 31 - 40	75.0	9.3	59.4	1.2	70.0	10.7	56.3	2.3	60.0	0.0	59.0	1.9
▪ 41 - 50	70.2	9.3	60.1	3.8	67.0	9.6	60.0	5.7	65.5	10.9	61.8	7.0
▪ 51 +	74.4	9.9	58.2	6.1	65.7	10.2	58.1	9.5	69.8	13.1	66.0	8.3
F (P)	1.6 (0.329)		10.1 (0.000)*		0.88 (0.452)		0.49 (0.692)		4.6 (0.004)*		2.7 (0.044)*	
Gender												
▪ Male	73.8	9.1	58.3	4.2	65.7	8.1	58.9	8.2	68.9	12.6	65.2	6.8
▪ Female	71.5	10.6	60.0	6.4	67.5	12.3	58.3	7.7	65.6	11.3	62.2	9.1
t (P)	1.6 (0.107)		2.1 (0.035)*		2.9 (0.004)*		2.1 (0.035)*		0.33 (0.745)		1.8 (0.066)	
Education level												
▪ Illiterate	76.9	8.0	57.5	2.7	65.7	9.2	54.6	7.6	67.6	11.1	68.0	7.1
▪ Read & write	71.3	10.7	59.5	7.1	68.1	11.9	59.1	9.6	67.2	13.2	64.0	8.8
▪ Secondary	72.6	9.7	59.3	4.2	65.7	8.6	60.5	4.5	66.3	11.0	61.8	6.1
▪ University	68.0	3.6	60.0	2.2	62.2	3.4	61.7	9.3	77.8	13.8	60.0	9.5
F (P)	6.9 (0.000)*		3.5 (0.016)*		1.1 (0.338)		1.3 (0.283)		3.0 (0.030)*		7.0 (0.000)*	
Marital status												
▪ Single	80.0	0.0	60.0	0.0	80.0	0.0	60.0	0.0	60.0	0.0	60.0	0.0
▪ Married	72.7	9.8	58.9	5.3	66.2	9.9	58.6	8.1	67.7	12.2	64.1	7.9
t (P)	1.9 (0.056)		2.7 (0.007)*		0.77 (0.440)		1.6 (0.110)		2.3 (0.020)*		1.0 (0.311)	
Job status												
▪ Worker	74.8	7.8	58.8	4.8	67.3	8.9	60.0	6.5	72.0	14.0	63.6	7.4
▪ Employee	69.0	9.3	57.5	4.7	65.6	8.3	60.4	7.4	60.6	4.4	59.0	3.4
▪ Farmer	74.7	9.5	56.9	3.8	64.8	8.4	56.7	7.0	68.1	12.3	67.3	6.2
▪ Retired	74.7	8.3	62.5	2.2	68.9	9.1	58.3	14.4	75.6	12.4	64.0	9.5
▪ House wife	72.2	11.2	61.6	6.2	67.8	13.2	58.8	8.8	67.8	12.8	64.2	10.0
F (P)	1.9 (0.120)		3.4 (0.010)*		4.1 (0.003)*		0.85 (0.493)		4.4 (0.002)*		5.6 (0.000)*	
Number of Children												
▪ >3	72.4	9.8	60.3	6.6	66.0	12.1	60.5	9.5	67.0	11.2	62.4	10.2
▪ <3	72.9	9.8	58.3	4.3	66.3	8.7	57.7	7.1	68.0	12.7	64.9	6.4
F (P)	1.1 (0.285)		3.3 (0.001)*		0.61 (0.541)		1.8 (0.075)		2.5 (0.013)*		1.4 (0.173)	
Residence												
▪ Rural	74.4	10.0	58.9	5.8	67.8	9.3	58.7	8.1	69.7	13.7	66.6	8.3
▪ Urban	70.7	9.1	59.1	4.3	64.5	10.7	58.6	7.9	64.5	8.7	60.3	5.6
t (P)	3.9 (0.000)*		3.4 (0.001)*		1.4 (0.161)		1.3 (0.183)		3.3 (0.001)*		4.5 (0.000)*	
Family income status												
▪ Sufficient	73.8	9.8	58.7	6.3	65.6	10.4	58.7	9.6	69.8	13.1	65.4	8.7
▪ Not sufficient	71.5	9.6	59.3	3.2	67.6	9.4	58.7	4.8	64.4	9.9	62.0	6.1
t (P)	0.64 (0.525)		1.4 (0.172)		2.1 (0.038)*		1.7 (0.087)		0.77 (0.441)		0.61 (0.545)	

F: One way ANOVA * $P < 0.05$ (significant) T: Independent samples t test

Table (6): Distribution of the mean and standard deviation of the HRQoL of studied health-domains of HCV patients on interferon therapy, according to medical records data

Biomedical data	Tiredness		Emotional		Abdominal signs		Anxiety		Physical activity		General symptoms	
	Mean	±SD	Mean	±SD	Mean	±SD	Mean	±SD	Mean	±SD	Mean	±SD
Disease period												
▪ <3 year	20.4	3.8	31.5	6.3	10.1	3.2	13.9	3.5	12.7	2.3	19.5	4.3
▪ 3-6	21.0	3.3	32.7	4.9	10.5	2.3	14.3	3.9	12.6	2.3	20.6	3.7
▪ <6	15.0	0.0	40.0	0.0	15.0	0.0	16.0	0.0	6.0	0.0	25.0	0.0
F (P)	1.5 (0.222)		1.4 (0.220)		1.6 (0.202)		0.33 (0.718)		4.3 (0.016)*		1.7 (0.184)	
Hospital admission												
▪ Yes	20.2	3.1	31.1	4.8	10.0	3.2	13.5	3.6	12.5	2.2	19.5	4.2
▪ No	20.8	4.0	32.8	6.5	10.5	2.6	14.5	3.7	12.8	2.5	20.3	4.1
t (P)	0.96 (0.338)		1.6 (0.102)		0.91 (0.365)		1.5 (0.126)		0.61 (0.546)		1.1 (0.259)	
Family history												
▪ Yes	21.3	2.7	33.3	5.2	10.5	2.9	14.6	3.6	12.8	2.4	20.8	4.0
▪ No	20.0	4.2	30.9	6.2	10.1	2.9	13.6	3.6	12.5	2.3	19.2	4.1
t (P)	1.9 (0.050)*		2.3 (0.026)*		0.70 (0.483)		1.5 (0.141)		0.86 (0.391)		2.1 (0.043)*	
Liver condition												
▪ Efficient	20.1	3.5	31.2	6.0	9.5	2.8	13.4	3.6	12.5	2.3	19.5	4.0
▪ Inefficient	21.4	3.7	33.5	5.4	11.7	2.7	15.4	3.3	13.0	2.5	20.8	4.4
t (P)	1.8 (0.067)		2.1 (0.044)*		4.2 (0.000)*		3.1 (0.003)*		1.1 (0.254)		1.6 (0.105)	

F: One way ANOVA; T: Independent samples t test; * $P < 0.05$ (significant)

Table (7): The mean and standard deviation of HRQoL of HCV control group patients, according to the medical records data

Biomedical data	Tiredness		Emotional		Abdominal signs		Anxiety		Physical activity		General symptoms	
	Mean	±SD	Mean	±SD	Mean	±SD	Mean	±SD	Mean	±SD	Mean	±SD
Disease period												
▪ < 3 year	68.8	8.4	57.7	5.2	64.1	11.1	56.7	7.2	62.5	4.9	59.8	5.1
▪ 3 - 6 years	72.8	9.6	59.3	4.0	68.3	9.0	60.4	7.8	69.2	14.1	63.2	6.1
▪ > 6 years	78.7	9.1	60.2	6.7	66.7	9.6	58.7	8.8	72.0	13.6	71.2	8.9
F (P)	10.4 (0.000)*		2.1 (0.131)		2.0 (0.137)		2.5 (0.084)		6.6 (0.002)*		26.7 (0.000)*	
Hospital admission												
▪ Yes	76.7	9.7	60.8	5.2	69.9	9.8	59.5	8.1	72.6	14.2	66.3	8.7
▪ No	69.3	8.5	57.3	4.7	63.2	9.2	57.9	7.9	62.8	7.2	61.8	6.4
t (P)	4.4 (0.000)*		3.9 (0.000)*		3.9 (0.000)*		1.1 (0.281)		4.9 (0.000)*		3.3 (0.001)*	
Family history												
▪ Yes	76.8	8.2	59.5	6.0	67.5	9.0	60.5	8.1	73.1	13.9	67.9	8.4
▪ No	68.4	9.6	58.3	4.2	65.2	11.0	56.6	7.4	61.2	4.4	59.6	4.1
t (P)	5.1 (0.000)*		1.3 (0.201)		1.4 (0.218)		2.7 (0.008)*		6.2 (0.000)*		6.7 (0.0000)*	
Liver condition												
▪ Efficient	72.2	9.0	58.6	4.7	65.8	10.1	60.1	7.0	69.1	12.6	63.2	7.2
▪ Inefficient	74.8	11.6	60.0	6.5	68.3	9.7	54.7	9.2	63.3	9.6	66.3	9.4
t (P)	1.2 (0.204)		1.3 (0.190)		1.3 (0.214)		3.4 (0.001)*		2.3 (0.021)*		1.9 (0.060)	

F: One way ANOVA; T: Independent samples t test; * $P < 0.05$ (significant)

emotional (t=3.9, $P = 0.000$), abdominal signs, (t=3.9, $P = 0.000$), physical activity, (t=4.9, $P = 0.000$), and general symptoms, (t=3.3, $P = 0.001$). Concerning family history of control patients for the disease, patients who had family history of the disease,

Hospital admission for this group of patients reported higher means and standard deviations for all studied health domains compared to non-hospitalized subjects, significant differences were reported for health domains of tiredness (t=4.4, $P = 0.000$), role

therapy patients, acquired their HCV during the same disease period. No significant difference between the two compared groups, regarding hospitalization of HCV patients due to severity of the disease. In contrast to the control group patients, half of who on therapy participants had family history of HCV infection. In accordance to this present study findings, at baseline study of chronic HCV patients, the majority of the subjects with HCV had acquired their infection through intravenous drug using had disease duration of 25 years and the mean disease duration since stopping drug was 14-years, as compared to those who had been infected by blood transfusion indicating much gain of this group patients from treatment.[40] Thus, many of infected patients had genotypes 2 and 3viral infection which response well to interferon therapy.[50,51] In contradictory, another study assumed that the results drawn from participants assessed retrospectively, showed that the relative severity of their health status at three different points at time to five years ago , did not differ significantly between the two compared group.[45]

The HRQoL is often impaired due to the impact of disease and/or treatment on a patient's physical, emotional and social functioning.[37]Several studies have shown that HRQoL is impaired in patients with chronic liver disease (CLD) and within this group, patients with chronic HCV experienced the lowest HRQoL.[34,38,52-56] This impact seems to be most clear in the health domains of social, physical functions, general health and vitality.[57] In the hight of the importance of HRQoL measurement of the HCV health status, the study used CLDQ[34] to assess the HRQoL of the studied subjects. Among the findings patients of age group 51years and above of the on therapy group had higher means ± SD values of HRQoL for the health-domains of tiredness, role emotional and anxiety. Where, control group patients showed significant differences for role emotional, physical activity and general symptoms among different age groups. The study also observed significant gender differences for the both compared groups in the favour of females for the domains of tiredness, abdominal signs, and anxiety and general symptoms of the study group patients. While control group showed significant differences for the domains of role emotional and abdominal signs for females and anxiety for males. The influence of age on the HRQoL of HCV patients either on antiviral therapy or not was also mentioned by a Greek study among chronic HCV patients, where age was positively associated with mental health and vitality,[12,24] although the study noticed that patient's HRQoL was worse than that of healthy individuals and fluctuated significantly during treatment, that was possibly due to interferon treatment. Similar findings were also mentioned in a

recorded higher means ± SD for all studied health domains with significant differences of tiredness, anxiety, physical activity and general symptoms, (t= 5.1, *P* =0.000, t=2.7, *P* =0.008, t=6.2, *P* =0.000, and t= 6.7, *P* =0.000, respectively). On the other hand, patients with good liver conditions of this group of study, recorded higher means ± SD, with significant differences for health domains of anxiety, (t=3.4, *P* =0.001) and physical activity, (t=2.3, *P* =0.021). No significant differences were detected for the rest four studied health domains**.

4.Discussion

This study explored the impact of Pegglated interferon (PEG INF)-based antiviral treatment with various patients socio-demographic characteristics and medical records of hepatitis C virus (HCV) on healt-related quality of life,(HRQoL) of HCV patients. Then comparing the impact of HCV infection on the HRQoL of HCV patients on therapy and (control group). The study showed that the majority of the patients on therapy were among age group 31-40 years. More than half of the control subjects were among age group 50 years and above. The illiteracy was higher among on therapy patients, and two-thirds of them had no sufficient income. The study also observed that three-quarters of this group patient were rural residents. In contrast, the majority of the control group, was educated, and was married. One-third of them was wealthy with sufficient income, and had less than three children. These findings were in line with results of studies from Egypt and Pakistan on chronic hepatitis C virus (CHCV), among rural people with HCV. The studies mentioned that the highest prevalence among rural population and several confounding factors of the association of HRQoL and HCV infection, older age, male sex [45] and low educational level,[46] these factors in turn decreased consistently the HRQoL of patients .[47] .Similar findings among Egypt Delta patients were reported that nearly two-thirds of HCV patients were males with mean age of 43.5 years, and more than two-thirds of the participants were illiterate and had only primary education level. More than half of them lived in urban in contrast to our finding of majority of rural residents were infected. While the coincidences to the study findings, were in marital status and income of the participant. [45, 48, 49] The argument of these results was the report that found about weak association between HRQoL and the level of education as well as marital status. This argument was due to better socio-economic status of highly educated patients and less emotional distress among married subjects.[46)

The present study found that, the patients who acquired HCV within the duration of 3 to 6 years, were higher among the control group compared to on

abdominal symptoms, physical activity emotional upset.[36,48]

Conclusion:

This study concluded that the majority of the study group patients were among the age group, 31-40 years, and more than half of the control group patients were among age group of 51years and above. Nearly half of the on therapy subjects were illiterate or had more than three children and about two-thirds of them had no sufficient income. It was noticed that three-quarters of patients on therapy were rural residents. On the other hand, the majority of the control group patients had better education level, and had married. Also, one-third of this group patient was wealthy with sufficient income and had less than three children. The majority of the on therapy patient had high level of HRQoL scores for all the studied health-domains. While the majority of the control HCV patients had moderate level of HRQoL scores for the domains of role emotional, abdominal signs, anxiety, physical activity and general symptoms. Two-thirds of this group patient showed, high level in the health-domain of tiredness. More than three-quarters of the on therapy patients had high level of overall health and control group patients had moderate level of overall health.

Patients age group 51years and above of the on therapy patients had higher means ± SD values of HRQoL for the health-domains of tiredness, role emotional and anxiety. While the control patients showed significant differences among different age groups for the domains of role emotional, physical activity and general symptoms. The study reported significant gender differences for both studied groups of study in the favor of females for the domains of tiredness, abdominal signs, and anxiety and general symptoms for the on therapy patients. While control group patients showed significant differences for the domains of role emotional and abdominal signs, for females and anxiety health-domain for males. The study revealed that no significant differences were found between the studied durations of disease of HRQoL of the on therapy patients, except for the domain of physical activity, (P=0.016). While the control group patients with HCV more than 6-years, showed significant differences for the health-domains of tiredness, physical activity and general symptoms, (P =0.000, P =0.002 and P =0.000), respectively). On therapy patients who had family history of HCV infection reported significant differences for the health-domains of tiredness, (P =0.05), role emotional, (P =0.026) and general symptoms, (P =0.043), compared to counterparts who had no family history of the disease. On the other hand control subjects with family history of the HCV disease, reported higher mean ± SD values for all studied health-domains,

hospital based study where patient's age negatively affected, scores tiredness/fatigue, mental health and perception of pain.[48,58] In contrast to the current findings of gender difference, women tended to have lower HRQoL scores,[41] a finding that has been reported even among healthy subjects,[23] and in HRQoL male patients are enjoy better life than female patients.[48] In another study mean sickness impact profile (SIP) was unchanged or slightly worsened in untreated control patients.[33] Men and women differed in the course of HRQoL with an increase on scores of men for all dimensions except for general health.[59,60] Thus, therapy with interferon and ribavirin might have more intense and more prolonged impact on females due to anemia during antiviral therapy.[60]

The current study showed that the acquisition of infection periods of study patients did not differ significantly, except for the health domain of physical activity. On the other hand, control patients showed significant differences for the domains of tiredness, physical activity and general health. No significant differences were observed concerning hospitalization status. Outpatients of the control patients showed significant differences, for health domains, tiredness, role emotional, abdominal signs, physical activity and general symptoms. While who on therapy subjects and had family history of the disease, reported significant differences for the domains of tiredness, role emotional and general symptoms. While control subjects who family history of the disease had showed significant differences for the domains of tiredness, physical activity and general symptoms. Comparing liver conditions of the HCV patients on the HRQoL of patients on therapy and control HCV patients, the former group of patients who had impaired liver conditions, reported higher means ± SD values with significant differences for the health domains of role emotional, abdominal signs, and anxiety. Oppositely to the control subjects who had good liver conditions, showed significant differences for the domains of anxiety and physical activity compared to their counterparts of other liver conditions. A study comparing duration of HCV acquisition and older ages, according to mode of transmission of the disease, reported significant lower scores for the health domains of social functioning, mental health and the mental components summary scores [40] and who had acquired HCV infection for longer durations, seemed to have lower HRQoL scores in contrary to our findings. [12] Chronic liver condition causes significant impairment in the QoL index (QoLI), among Pakistani patients with HCV. Patients who had advanced liver impairment showed significant lower CLDQ scores, and decrease in five out of the six HRQoL domains' scores ; namely, fatigue/tiredness, systemic symptoms,

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compared to their counterparts, and had significant differences for, tiredness, (P =0.000), anxiety, (P =0.008), physical activity (P =0.000), and general symptoms, (P =0.000).

Recommendations

- The study recommends including HRQoL assessment as a primary outcome in clinical trials, and how to use the information drawn in the benefit of HCV patients.

- It is recommended to conduct studies that measure patient-oriented, as to interpret HRQoL data in HCV to avoid underestimating the true burden of illness engendered by HCV infection.

- Nurse and medical team need to focus more on the impact of HCV therapy on the QoL of their patients to help maintain adherence to therapeutic regimen and in order to better understand the true impact of HCV on patients, their families and environments.

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