IOSR Journal of Nursing and Health Science (IOSR-JNHS)
e-ISSN: 2320–1959.p- ISSN: 2320–1940 Volume 6, Issue 5 Ver. III. (Sep. -Oct .2017), PP 23-29
www.iosrjournals.org

Quality of Life for Patients with HepatitisCviruses Undergoing New Modalities

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Abstract: *The incidence of the hepatitis C virus (HCV) is 2.8%Worldwide, causing a significant global burden of morbidity and mortality. According to a nationally representative survey carried out in 2008, Egypt has the highest HCV prevalence in the world; with 14.7% prevalence among the 15–59 years age group. This study aims at assessing quality of life for patients with HCVviruses undergoing new modalities. A descriptive exploratory research design was utilized in the study. The study was conductedat outpatient clinics at Hepatic Viruses Center at Cairo University Hospital. A convenience sample of (100) male and female HCV patients undergoing new modalities were included in the study. Data was collected using a Bio-socio demographic sheet,and Health Related Quality of Life Questionnaire (HRQOL). The result revealed that,there were statistically significance differences pre, during, and post treatment regarding all aspects of quality of life. The study concluded that, a significant improvement in HRQOL across the three different time period among patients with HCV treated by new modalities. The current study recommended that, Health Insurance should be available to all patients to meet the cost of medications. As well as health awareness and screening for all patients and family members to protect them from HCVshould be available.*In addition to vaccinate all patient with HCV with hepatitis B vaccine(HBV).

Key words: Hepatitis C Virus, new modalities, Quality of life, Hepatitis B vaccine

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Date of Submission: 26-09-2017 Date of acceptance: 20-09-2017

I. Introduction

Hepatitis C virus (HCV) infection is a major global health challenges, it is estimated that more than 80 million people are chronically infected worldwide, with 3-4 million new infections and 350 000 deaths occurring annually because of its complications **(Guerra, et al. 2012[1], Miller, et al.2015[2], and Kandeel, et. al. 2016[3]).**

In Egypt, the situation is very critical.HCV is considered an epidemic in Egypt. The bloodborne virus, which is highly infectious, infects at least 1 in 10 of the population aged 15-59.Egypt is the country with the highest HCV prevalenceinthe world; in 2008, the Egyptian DemographicHealthSurvey (EDHS), which was conducted on a largenational representative sample, estimated the prevalenceof HCV antibodies and HCV RNA,among the 15–59 yearsage group, to be 14.7% and 9.8% respectively. Basedonthe population census and the EDHS done in 2008,itwas predictable that more than 6.8 million personsaged15–59 years had HCV antibodies, of which morethan4.5 million individuals had active HCV infection**(Amer, et.al.2015 [4];Okasha, et al.2015[5] and Youssef, et al.2017[6]).**

Some age groups suffer prevalence rates of up to 50%. As for the geographical distribution of anti-HCV in persons aged 10-50 years: the Nile Delta and Upper Egypt have rates of 28% and 26% respectively.Incidence rates are probable at 2-6 people per1000 per year, that is, at least 170,000 new cases every year, which means continuing a prevalence rate of 5-15% in the near future. Liver mortality in Egypt spreads 40,000 per year, making 10% of total mortality, and comes second after heart diseases**(Gaber, 2014[7]).**

At the end of 2013, Gilead Sciences gained the Food and Drug Administration (FDA) approval of its new oral Direct Acting Antiviral (DAA) called sofosbuvir (SOF), a nucleotide polymerase inhibitor. This new class of antivirals is a breakthrough in HCV treatment because they areadministered orally, whereas interferon (INF) is administered via subcutaneous injection. The importance of Gilead's sofosbuvir lies in its role as a "backbone" of many oral HCV regimens in clinical trials, which apply to all HCV genotypes, including genotype-4, the one most prevalent in Egypt **(Odilon and Karyn.2014[8]&Lam, and Salazar, 2016[9]).**

Egypt has the highest prevalence of chronic HCV infection, With the current new modalities antiviral therapy, which is anticipated to cure more than 90% of chronic infection within a short duration, Egypt has started treating a large number of infected persons through 23 national treatment centers with a schedule that

includes the new antiviral agent,sofosbuvir. To assess the population impact of this national treatment programme **(Mostafa,et.al. 2016[10]).**Because treatment using sofosbuvir-based combinations is usually shorter (6 to 24 weeks), it's more effective and requires less monitoring.Besides, compared to interferon, it has less and milder side effects. Sofosbuvir-based combinations have very high cure rates of over 90% in some groups;new treatment modalities and guidelines for acceptance with the national treatment programme were announced by the Ministry of Health. Two treatment modalities were announced: 1) Pegylated interferon (peg-INF) + ribavirin + sofosbuvir for 3 months 2) Sofosbuvir + ribavirin for 6 months (for patients who are intolerant to INF)**(Gaber, 2014[7]&Hossam,2014[11]).**

Quality of life has become an important outcome variable in clinical research and a vital factor in treating HCV. The burden of HCV infection is not limited to the impact of cirrhosis and hepatocellular carcinoma. Research has established that HCV infection is associated with reduced Health-Related Quality of Life (HRQOL). The HRQOL burden of HCV infection in the United States hasbeen widely reported **(Younossi, et al.2007 [12]&El Khoury, et al.,2014[13]).**

Hepatitis C is associated with reduced HRQOL as manifested by the disturbance of physical, social, mental, and behavioral aspects of well-being and so lead to physical and psychological problems.Patients living with HCV have a significant reduce in their QOL, although treatment success can improve this negative effect**(Mannes,2013[14]).**

The aim of the study was to assess the effect of QOL for patients with HCV undergoing new modalities through:

1. Assess the quality of life for patients with HCV undergoing new modalities(pre, during, and post treatment).
2. Explore the relation between the period of treatment and improvementlevel of QOL.

Research questions:

Q1. What are the QOL for patients with HCV undergoing new modalities?

Q2. What are the relation between the period of treatment and improvement level of QOL?

II. Subjects and Methods

2.1.Research Design: A descriptive exploratory research design was utilized in the current study.

2.2.Setting: The study was conducted at the outpatient clinics at Hepatic Viruses Center in Cairo University Hospital.

2.3. Sample: A convenience sample includingall adult patients (male, female) were included in the study. With the following inclusion criteria: Adult patients (≥ 18 years), of both genders, treated by new modalities. The treatment started at January 2016 to August 2016.

2.4.Tools of data collection: Two tools were utilized in the current study.

2.4.1.Bio-Socio Demographic Sheet: The sheet wasdeveloped by the researchers in English language, after reviewing the related current national and international literature. It involvedcharacteristics of the patients under study such as: age, gender, marital status, education level, occupation, income, cost of treatment, and family history. **The items of this sheet were adopted from,Tscheschlog, and Jauch,(2007[15]), Kirk,andO'Kshea,(2011[16]), and Doyle et al. (2016)[17].**

2.4.2.Health related Quality of life questionnaire(HRQOL)(SF-36):

HRQOL is a systematic tool to assess quality of life of HCV patients. (SF-36) is an instrument universally used to assess HRQOL. (SF-36) questionnaire consists of 25 questions and 36 items covering eight domains: physical functioning, physical aspects, bodily pain, general health perceptions, vitality, social functioning, emotional functioning and mental health. The individual received a score in each domain, ranging from zero to 100, with zero being the worst and 100 the best.The items of (SF-36) approved by **Martino,(1997) [18].**

III. Tools Validity and Reliability

Tools developed by the researchers (tool 1)was examined by a panel of three experts in the field of medical surgical nursing to determine the included items are clear and suitable to achieve the aim of the study. The second tool is a standardized which used by the researchers(SF-36) HRQOL questionnaire.It measures eight main domains: (a) general health (GH); (b) physical functioning (PF); (c) limitation of roles due to physical problems, known as role-physical (RP); (d) limitation of roles due to emotional problems, known as role-emotional (RE); (e) social functioning (SF); (f) bodily pain (BP).

IV. Pilot Study

A pilot study was done on 10 patients(10 % of the study sample) to test clarity, applicability, feasibility, ant estimate the need time to complete each tool. Needed modifications were done in data collection tools and subjects included in the pilot were excluded from the main study sample.

V. Protection Of Human Rights

Official permission was obtained before conduction of the study from the medical and nursing director of outpatient clinics at Cairo university hospital. Participants in the current study were voluntary. Written consents were obtained from patients who met the inclusion criteria. The participants have the right to withdraw from the study at any time without giving any reasons.

VI .Procedure

This study was carried out on two phases: preparatory and implementation phases. Regarding preparatory phase, it was concerned with authoritative arrangements to carry out the study in addition to structure and organization of different data collection tools, and selection of the study setting. Once official permissions were obtained, the researchers started the implementation phase. The process of data collection was carried out from January 2016 and completed by August 2016. In order to assess HRQOL, of all the participants responded to the (SF-36) HRQOL questionnaire. The questionnaires were used to interview patients with the HCV undergoing new modalities in outpatient clinic pre-starting the new modalities (as baseline), and after month 3(during), and then 6 months from starting therapy(post).

Outpatient clinics at Hepatic Viruses Center at Cairo University Hospitalwas visited by the researchers two days a week from 9 am to 2 pm to meet 5-7 patients each visit, and spend about 40 -60 minutes with each patient, each researcher met about 3-4 patients each visit. The research took 8 months.The patients with positive Hepatitis C who accepted to share in the study after being oriented about the purpose and nature of the study were selected (adult, treated by new modalities) according to inclusion criteria. The researchers were able to complete the interviews using these instrumentsin 40 to 60 minutes. Each patient was interviewed three times (pre-treatment, at month 3(during), and after month 6(post treatment).

VII. Statistical analysis:

Data was analyzed using Statistical Package for Social Science software (SPSS) version 20 for windows, mean, standard deviation,ANOVA. Probability level was set at $P \leq 0.05$ for all tests.

VIII. Results

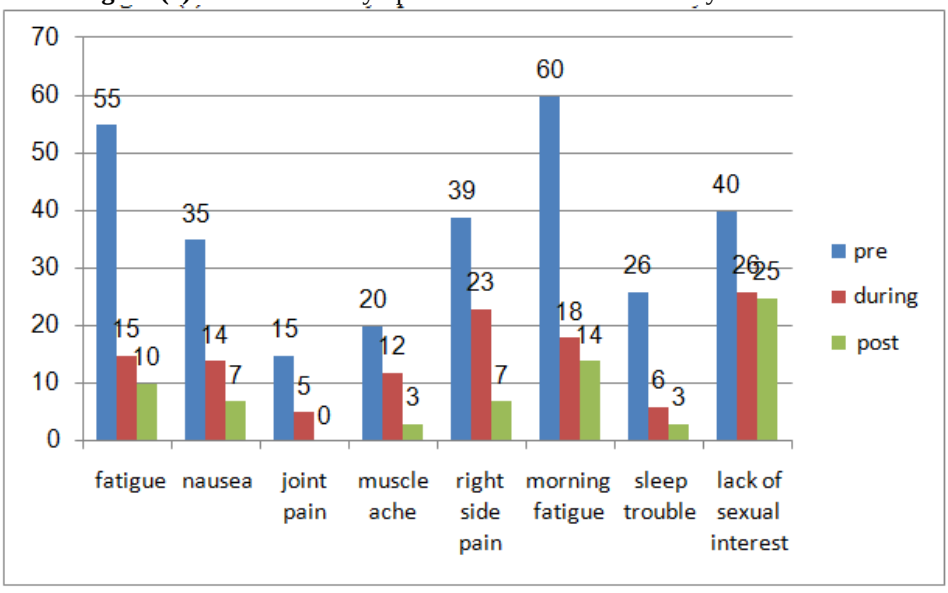
Table (1): Bio-Socio-demographic characteristics of patients in the study (n 100):

Items	No.	Percent%
Age (years):		
18<24	20	20.0
25<44	33	33.0
45<65	47	47.0
	41.33±14.54	
Gender:		
Males	63	63.0
Females	37	37.0
Marital status:		
Single	48	48.0
Married	40	40.0
Divorced	6	6.0
Widow	6	6.0
Educational level:		
Educated	64	64.0
Read and write	24	24.0
Illiterate	12	12.0
Occupation:		
Employed	46	46.0
Not employed	54	54.0
Occupation after infection:		
Full time	21	21.0
Part time	16	16.0
Can't work	9	9.0

Income:		
Sufficient for treatment	33	33.0
Insufficient	67	67.0
Cost of treatment:		
Health insurance	59	59.0
Free	41	41.0
Therapy duration:		
3 months	22	22.0
6 months	73	73.0
> 6 month.	5	5.0
Effect of disease on patient role in the family:	41	41.0
Yes	59	59.0
No		
Affection of patient role:		
Financial	10	10.0
Psychological	20	20.0
Social	8	8.0
Physical	3	3.0
Family history of HCV:		
Yes	26	26.0
No	74	74.0
Patient relation with affected person:		
1st	26	26.0
2nd.	0	0.0

Table(1) shows that, the study subjects consisted of 100 adult patients males and females, the bio-sociodemographic data of the present study, as regards to age revealed that (47 %) of patients their age werebetween 45-65 years, the mean age was 41.33±14.54.Concerning gender, (63%) of patients were males, and (52%) were married. As regards to educational level, (64%)of patients were educated, and (46%) of patients were employees,while (21%) of patients have full time jobs. As regards toincome (67%) of patients have insufficient income. In addition to 59%) treated in health insurance. Concerning duration of therapy (73%) of patients treated for 6 months. Regarding the effect of diseases on patient role (59%) of patientsthe disease has no effect on patients'roles in the family. While (20%) of patients,the disease affected their psychological states. Regarding, family history (74%) of patients have no family history to HCV, while (26%) of patients have family history to HCV from the first line of relation.

Figure (1): Patients with symptoms that interfere with daily life activities:



Figure(1) reveals that,here was a great interference and affection of symptoms on the activitiesof daily living before starting treatment may reach to 60% of affection related to feeling with morning fatigue, while the interference decreases to be a maximum of about25% related to lack of sexual interest and decreased more and improved to be zero% related to joint pain and maximum 24% related to sexual interest.

Table (2): Mean scores of eight domains of Health-Related Quality of Life (HRQOL) Questionnaire of HCV:

Domains	Pre.	During	Post.	F	Sig.
• Physical function	57.50±34.9	72.75±26.85	92.75±13.89	43.9	0.000
• Role limitation of physical function	50.48±20.3	74.62±14.02	94.7±3.08	237.8	0.000
• Bodily pain	47.0±24.8	56.30±20.92	82.40±13.26	82.2	0.000
• General health	55.03±14.9	65.38±14.83	82.25±7.19	114.5	0.000
• Vitality- energy- fatigue	44.39±19.45	57.13±15.50	79.78±9.26	136.7	0.000
• Social functions	53.70±17.054	70.22±16.17	84.83±12.16	103.9	0.000
• Role limitation of social activities	45.32±18.88	58.91±15.99	81.07±13.39	123.5	0.000
• Mental health- emotional wellbeing	41.9±20.15	55.52±15.12	76.40±8.6	127.3	0.000

** Highly statistically significant difference at p<0.001

Table (2) clarifies that,there were highly statistically significant differences between pre during and post treatment mean scores in the quality of life of patients regarding physical function, role limitation of physical function, bodily pain, general health, vitality-energy-fatigue, social function, role limitation of social activities, and mental health-emotional wellbeing(F = 43.9, 237.8, 82.2, 114.5, 136.7, 103.9, 123.5, 127.3 respectively at P <0.001).

IX. Discussion

Concerning bio-sociodemographic characteristics of patients in the study subject, it was obvious that nearly half of patients in the study subject their age were between 45-65 years. The mean age was 41.33±14.54. This result is supported by**Fábregas,et al. (2013)[19],** who found in his study to assess HRQOL with chronic hepatitis C, the majority of patientsmean age was 50.6±11.3.So, patients who suffer from HCV are in middle adulthood which is the productive age for both family and society. In the current study, the majority of patients were male and half of patients were married.This result issupported by **Chang, et al. (2014)[20]** in his study to assess HRQOL for a patient treated byantiviraltherapy in Taiwan, he found that around half of the patients were male and the majority of the patients were married and live with their families. In this study, the majority of the patients were educated and less than half are employees. This result is in agreement with **Chang, et al. (2011) [21],** who explained that over half of patients had an educational level above junior high school, and more than half were currently employed.From the researchers' point of view the HCV patients were fatigued because of their illness, this may affect in the productivity of patients at work.Regarding the cost of medication, the current study explained that, the majority of patients have insufficient income to meet their basic needs, rather than the cost of medication. **Armstrong, et. al (2016)[22]** shows that, HCV therapy with interferon or combination therapy with interferon and ribavirin are costly.

From the researchers' point of view,the patient's income is not sufficient to satisfy the patient's needs, as well as less than half of the patientsaren't employees andhad part time job or didn't have a job at all. As regards patients' symptoms that interfere with daily life activities, the current study showed that fatigue was the most common symptoms that affected daily life activities at the beginning of treatment then decreasesgradually at the end of treatment regimens. These findings are in agreement with **Malhorta, et al. (2016)[23],** whomentioned that, fatigue is the most common symptom relatedto QOL of HCV undergoing sustained virologic response (SVR).In this study, the third symptom which affect patients were their complaints of their daily life activities were lack of sexual interest, which improved at the end of treatment. This result is in agreement with **Malhorta, et al. (2016)[23]** who mentioned that, the majority of the patients in his study werenot satisfied with their sexual interest. Health–Related Quality of Life (HRQOL) is increasingly recognized as an important methodfor assessing the load of chronic illness. Researchers identified that HCV infection significantly reduces HRQOL, even in the absence of cirrhosis, and proper treatment of HCV is associated with an improvement in HRQOL **(Mandorfer et al. 2014) [24].** Concerning HRQOL, the current study revealed that there are highly statistically significant differences regarding all aspect of HRQOL (Physical function,Role limitation of physical function, Bodily pain, General health, Vitality- energy- fatigue, Social functions, Role limitation of social activities, and Mental health- emotional wellbeing)among patients who were treated with new modalities pre, during , and after treatment regimens.

The present study finding was in agreement with **Younossi, et.al (2007) [12]**who clarified that, HRQOL in all its aspects improved in-patient with HCV when treated with antiviral therapy. On the other hand,**Gogolishvili&Globerman(2016) [25]**stated that, patients who were treated by new modalities for 12

weeks reported highly statistically significant improvement in their HRQOL after treatment in his study of HCV patients treated by new antivirus therapy without interferon.

Younossi et al. (2014) [26] stated that HRQOL is significantly improved when treated with oral interferon than interferon based therapy. Although there is a higher significantly improvement of HRQOL among patients treated by SOF + RBN when compared with standard regimen.

The clarification of the improvement of HRQOL of HCV patient treated by new modalities may be due to the less sideeffects of the new modalities, inhibition of virus and its effect, increase patient awareness regarding disease and medications, and better efficiency of treatment regimens in the clinical setting.**Younossi et al. (2015) [27]**showed that, chronic HCV patients who were treated with RBN- combing regimen for 8 weeks, their HRQOLwas positively changingand work productivity during the fourth week of active treatment.The change including the physical and social function well-beingand fatigue scale with astatistically significant improvement between pre, post and during the treatment regimens. There are disagreements on the current study finding and **Change et al. (2014) [20]**, whomentioned that, patients with Chronic Hepatitis C (CHC)undergoing antiviral therapy showed significantly lower scores in five scales and showed decrease in HRQOL compared with thepatients without antiviral therapy in his study that applied on Taiwanese among patientswith HCV.Also,the results are in the contrast with **Marcellin, et al (2011) [28]** who clarified that there is a reduction in HRQOL of patients with HCV at baseline and after antiviral treatment regimens.

X. Conclusion

This study found a significant improvement in HRQOL across the three different time periods among patients with HCV treated by new modalities. The study highlights the critical importance to assess the HRQOL for patients with HCV receiving new modalities.

XI. Recommendation

Based on the findings of current study, the following is recommended:

- Health insurance should be offered to all patients to meet the cost of medications.
- Follow up for all patients with HCV after treatment to avoid recurrence of infection.
- Health awareness through an educational program and screening for all patients and their family membersisessentialto avoid more infections with HCV.
- Vaccinate patients with HCV with hepatitis B vaccine to protect liver from other infection.

Acknowledgment

The authors would like to express their sincere gratitude to all patients with HCV and their family members for cooperation throughout the study period.The authors wouldlike to express their deepest gratitude and appreciation to the manager and nursing team at Cairo university hospital for their effort and cooperation.

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Manar Fathy Hamza. "Quality of Life for Patients with Hepatitis Cviruses Undergoing New Modalities." IOSR Journal of Nursing and Health Science (IOSR-JNHS) , vol. 6, no. 5, 2017, pp. 23–29.