## **Original Research Article**

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# Quality of life among hepatitis C patients on treatment, Minia, Egypt

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#### **ABSTRACT**

**Background:** Hepatitis C is a highly prevalent infectious disease among Egyptian population. Different types of interferon and antiviral drugs are used in the treatment and have significant side effects which may alter quality of life of the treated chronic hepatitis C patients. The aim of the study was to identify the course of and factors associated with HRQOL in HCV patients given standard treatment based and to assess its relation to socio-demographic and clinical characteristics.

**Methods:** This prospective consecutive hospital based study included 120 chronic hepatitis C patients in El-Minia city and by using SF-36V2 questionnaire.

**Results:** HRQOL baseline scores, general health had the lowest score, followed by vitality, while Role emotional had the highest score. Physical component summery scores (PCS) was slightly higher than mental component summery scores (MCS) for PCS. Subjects showed significantly lower SF-36 scores at the 12th week of treatment Compared to the pretreatment values. Mean scores of all SF-36 domains improved by the end of treatment, (p<0.01). Scales most affected during therapy were vitality (VT), general health (GH) and bodily pain (BP). The effect size (ES) observed on SF-36 subscales, the most affected dimensions at the 12th week of treatment were (PF, SF, VT and BP) (they were ≥0.8) could be considered large change, according to Cohen's criteria.

**Conclusions:** Subjects showed significantly lower SF-36 scores at the 12th week of treatment. Mean scores of all SF-36 domains improved by the end of treatment.

**Keywords:** Hepatitis C, Health-related quality of life, Therapy, Minia

## INTRODUCTION

Chronic hepatitis C (CHC) is an infectious disease caused by the hepatitis C virus (HCV). According to World Health Organization (WHO), around 250 million people globally are infected with HCV, and an estimated 71 million people have chronic hepatitis C infection, and around 170 million people are chronic carriers of the virus, which can lead to cirrhosis, liver failure, and hepatocellular carcinoma. Egypt has the largest burden of HCV infection in the world, with a 10% prevalence of chronic HCV infection among persons aged 15–59 years. HCV transmission is ongoing in Egypt and

incidence rates estimated between 2 and 6 per 1000 every year, (170,000 new infections annually). 4

Health-related quality of life (HRQOL), which reflects what patients are concerned with and what they experience, has been widely researched in patients with CHC. Pegylated interferon and ribavirin have significant side effect profiles that reduce quality of life. Anti-viral therapies are associated with a decline in HRQOL, which returns to baseline when therapy is terminated. Indeed, the impact on HRQOL and the adverse effects of antiviral treatment have been documented for Western populations. However, to our knowledge, such studies

have not been done for HRQOL in Egyptian patients with CHC.

#### **METHODS**

This prospective hospital based study included 120 chronic hepatitis C patients of them 63 patients attending the Interferon Unit in Samalot city and 57 attending the Health Insurance Hospital in El-Minia city from January 2014 to January 2016. The sample size was calculated according to Epi Info 2000 depending on the number of Minia population as 4,500,000 individuals, prevalence of hepatitis C infection as 20% and the confidence as 95%.

The study was conducted to assess the HRQOL and its relation to socio-demographic and clinical characteristics in HCV-infected patients (at the beginning, after 3 months, and at the end of receiving the interferon treatment using "SF-36V2 questionnaire".

#### Inclusion criteria

All patients who were above 18 years and clinically and laboratory assessed at the study site and found to be good candidates for receiving treatment (i.e. antiviral therapy in form of ribavirin and interferon) at health insurance hospital and the interferon unit in one day surgery hospital in Samalot district.

#### Exclusion criteria

CHC patients not receiving treatment, or who were already on interferon treatment during the emanation of the study.

All the participants in the study were interviewed to collect the following data:

1-Socio-demographic data: name, age, sex, residence, marital status, educational level and occupation

2-Quality of life: was assessed by using "SF-36V2 questionnaire". which measures health related quality of life (HRQOL). The previously validated Arabic version of the SF-36 questionnaire was used.

The SF36 questionnaire measures eight multi-item variables (physical functioning, physical role limitations, bodily pain, general health, vitality, social functioning, emotional role limitations, and mental health).

After the questionnaire being completed, and the resulting scores were transformed onto a scale of 0 (worst possible score) to 100 (best possible score), as recommended by the questionnaire's originators.

We calculated physical component summery (PCS) and mental component summery (MCS) online using US norm-based methods—in which the mean is 50 (SD, 10) in the 1998 general US population.

We calculated the effect sizes (ESs) which is simply a way of quantifying the size of the difference. It is particularly valuable for quantifying the effectiveness of interferon therapy. A HRQOL difference was calculated using the following equation (SD=standard deviation):

$$ES = \frac{(HRQOL_{group 1} - HRQOL_{group 2})}{SD_{group 1}}$$

According to Cohen's criteria (0.20–0.49 considered small, values of 0.50–0.79 considered moderate, and values  $\geq$ 0.80 considered large).

#### Statistical analysis

Data entry and analysis were all done using SPSS Version 18.0. Chicago: SPSS Inc. Graphics were done using Excel. Quantitative data were presented by mean and standard deviation, while qualitative data were presented by frequency distribution. Correlation, Chi Square, linear regression, one way-ANOVA and t test were done. The probability of less than 0.05 used as a cut off point for all significant tests.

#### **RESULTS**

This study included 120 chronic hepatitis C patients, of them 63 patients attending the Interferon Unit in Samalot city and 57 attending the Health Insurance Hospital in Minia city from January 2013 to January 2015. The age of the subjects attending the Interferon Unit ranged between 22-69 years (mean age was  $45.13\pm10.53$ ), while the age of the subjects attending the Health Insurance Hospital ranged between 30-65 years (the mean age was  $46.54\pm8.45$ ).

Table 1 showed the socio-demographic characteristics of the studied patients attending interferon unit in Samalot city. The study found that 81% were males, 81% lived in rural areas, 96.8% were married, 46% were below university, and 68.3% were employees, while patients attending Health Insurance Hospital 93% were males, 66.7% lived in rural areas, 96.5% were married, 59.6% were below university, and 82.5% were employees.

Table 2 showed that 26.6% of attending patients had other comorbidities. 47.5% of the study subjects under Reiferon retard drug, 39.2% of patients had high viremia, 43.3% of patients' fibrosis stage was F1 and 49.2% of patients' activity grade was A2.

In Table 3, it was found that the mean scores of the components of Short Form 36 (SF-36) (HRQOL) Questionnaire, general health had the lowest score  $(66.41\pm15.75)$  followed by vitality  $(69.57\pm21.84)$  while Role emotional had the highest score  $(94.30\pm21.33)$ . The table also showed that physical component scores (PCS) was slightly higher than mental component scores  $(52.7\pm7.33)$ .

Table 1: Socio-demographic characteristics of the studied chronic hepatitis C patients.

| Socio-demographic characteristics | Interferon<br>unit N (%) | Health<br>insurance<br>hospital N (%) |  |  |
|-----------------------------------|--------------------------|---------------------------------------|--|--|
| Sex                               |                          |                                       |  |  |
| Male                              | 51 (81)                  | 53 (93)                               |  |  |
| Female                            | 12 (19)                  | 4 (7.0)                               |  |  |
| Residence                         |                          |                                       |  |  |
| Urban                             | 12 (19)                  | 19 (33.3)                             |  |  |
| Rural                             | 51 (81)                  | 38 (66.7)                             |  |  |
| Marital status                    |                          |                                       |  |  |
| Married                           | 61 (96.8)                | 55 (96.5)                             |  |  |
| Not married                       | 2 (3.20)                 | 2 (3.50)                              |  |  |
| Educational level                 |                          |                                       |  |  |
| Illiterate                        | 10 (15.9)                | 1 (1.80)                              |  |  |
| Read and write                    | 4 (6.30)                 | 2 (3.50)                              |  |  |
| Below university                  | 29 (46.0)                | 34 (59.6)                             |  |  |
| University and above              | 20 (31.7)                | 20 (35.1)                             |  |  |
| Occupation                        |                          |                                       |  |  |
| Non worker                        | 9 (14.3)                 | 1 (1.80)                              |  |  |
| Farmer                            | 4 (6.30)                 | 1 (1.80)                              |  |  |
| Employee                          | 43 (68.3)                | 47 (82.5)                             |  |  |
| Free worker                       | 7 (11.1)                 | 8 (14.0)                              |  |  |
| Total                             | 63 (100)                 | 57 (100)                              |  |  |

Table 4 compared to pretreatment values, subjects showed significantly lower SF-36 scores at the 12th week of treatment. Mean scores of all SF-36 domains improved by the end of treatment, (p<0.01). However, did not reach to the pretreatment levels except for GH which significantly increased more than the pretreatment value. The effect sizes (ESs) observed on SF-36 questionnaire, the most affected dimensions at the 12th week of treatment were (PF, SF, VT and BP) (they were ≥0.8) could be considered large change, while mental health (MH) least affected (ES<sub>1</sub>=-0.3), according to Cohen's criteria. In addition, physical component scores more affected (ES<sub>1</sub>=-0.8, large change) than mental component scores (ES=-0.5, moderate change), But all dimensions improved by the end of treatment especially GH  $(ES_2=0.5)$  and VT  $(ES_2=-0.1)$ .

Figure 1 Effect sizes for SF-36 subscales at the 12th week of treatment and at the end of treatment among the studied chronic hepatitis C patients attending the Interferon Unit in Samalot city and the Health Insurance Hospital in Minia city from January 2014 to January 2016.

Figure 1, the effect sizes (ESs) observed on SF-36 subscales, the most affected dimensions at the 12th week of treatment were (PF, SF, VT and BP) (they were  $\geq$ 0.8) could be considered large change, according to Cohen's criteria. Generally, all subscales improved at the end of treatment especially in GH (ES =0.5).

Table 2: Clinical characteristics of HCV patients.

|   | Number  | Percent (%) |  |
|---|---------|-------------|--|
| Clinical characteristics                        | (n=120) |             |  |
| Type of interferon                              |         |             |  |
| Pegylated interferon alpha-2a (Pegasys)         | 27      | 22.5        |  |
| Pegylated interferon alpha-2b (pegintron)       | 36      | 30.0        |  |
| Pegylated interferon alpha-2a (Reiferon Retard) | 57      | 47.5        |  |
| Other comorbidities                             |         |             |  |
| Yes   | 32      | 26.6        |  |
| No  | 88      | 73.4        |  |
| PCR   |         |             |  |
| Low viremia                                     | 73      | 60.8        |  |
| High viremia                                    | 47      | 39.2        |  |
| *Fibrosis stage                                 |         |             |  |
| F1  | 52      | 43.3        |  |
| F2  | 39      | 32.5        |  |
| F3  | 29      | 24.2        |  |
| **Activity grade                                |         |             |  |
| A1  | 33      | 27.5        |  |
| A2  | 59      | 49.2        |  |
| A3  | 28      | 23.3        |  |

\*=Fibrosis was scored into 3stages: F1: indicating mild fibrosis F2: moderate fibrosis f3= severe cirrhosis; \*\*= Activity grade classified according: Grade 1 mild activity, Garde 2 moderate activity, Garde 3 severe activity.

Table 3: Mean health-related quality of life scores.

| SF-36 domains/ stages               | Mean ± SD    | min   | max   |
|-------------------------------------|--------------|-------|-------|
| Physical function (PF)              | 90.12±10.4   | 40    | 100   |
| Role physical (RP)                  | 90.41±27.15  | 0     | 100   |
| Bodily pain (BP)                    | 80.62±23.02  | 0     | 100   |
| General health (GH)                 | 66.21±15.46  | 25    | 100   |
| Mental health (MH)                  | 77.25 ±18.28 | 10    | 100   |
| Role emotional (RE)                 | 94.30±21.33  | 0     | 100   |
| Social function (SF)                | 85.33±20.60  | 50    | 100   |
| Energy/fatigue (vitality VT)        | 69.57±21.84  | 0     | 100   |
| Physical component<br>summery (PCS) | 52.7±7.33    | 24.30 | 67.40 |
| Mental component<br>summery (MCS)   | 52.2±8.28    | 17.90 | 65.70 |

## **DISCUSSION**

The study group enrolled 51(81%) males vs. 12(19%) females attending the interferon unit in Samalot city, while 53 (93%) males vs. 4 (7.0%) females attending the Health Insurance Hospital. This sex distribution of HCV in this study is in agreement with another studies which found that the prevalence of HCV was higher in males due to the fact that males were more susceptible to schistosomiasis than females as a result of farming work. <sup>9,10</sup> On the other hand, there were studies that did not

Support this gender difference and even slightly higher prevalence of HCV infection in females has been claimed. 11-13 Most of the patients were from rural areas, and this was in agreement with many studies which were

conducted among village residents in high HCV prevalence areas and reported the prevalence in rural areas averaged about 20%, higher than the national average. 14-15

Table 4: Mean scores of (HRQOL) effect size at different time of antiviral treatment among HCV patients.

| SF-36<br>domains/stages           | Before<br>treatment | At 12th<br>Week of<br>treatment | ES <sub>1</sub> | At the end of<br>Treatment | ES <sub>2</sub> | P 1    | $P_2$  | P <sub>3</sub> |
|-----------------------------------|---------------------|---------------------------------|-----------------|----------------------------|-----------------|--------|--------|----------------|
| Physical function (PF)            | 90.12±10.4          | 77.22±14.83                     | -0.9            | 84.40±11.73                | -0.5            | 0.0001 | 0.0001 | 0.002          |
| Role physical (RP)                | 90.41±27.15         | 57.56±43.85                     | -0.9            | 81.96±30.38                | -0.3            | 0.0001 | 0.1    | 0.0001         |
| <b>Bodily Pain (BP)</b>           | 80.62±23.02         | 56.09±30.52                     | -0.8            | 75.00±20.53                | -0.3            | 0.0001 | 0.02   | 0.0001         |
| General health (GH)               | 66.21±15.46         | 55.90±21.94                     | -0.5            | 74.75±17.15                | 0.5*            | 0.0001 | 0.1    | 0.0001         |
| Mental health (MH)                | $77.25 \pm 18.28$   | 70.00±21.74                     | -0.3            | 76.42±16.76                | -0.1            | 0.001  | 0.9    | 0.02           |
| Role emotional (RE)               | 94.30±21.33         | 69.45±42.64                     | -0.6            | 85.50±31.34                | -0.3            | 0.0001 | 0.06   | 0.002          |
| Social function (SF)              | 85.33±20.60         | 61.55±27.95                     | -0.9            | 74.70±21.77                | -0.5            | 0.0001 | 0.0001 | 0.001          |
| Vitality (VT)                     | 69.57±21.84         | 52.41±21.72                     | -0.8            | 68.45±18.35                | -0.1            | 0.0001 | 0.3    | 0.0001         |
| Physical component summary (PCS)  | 52.7±7.33           | 44.86±9.44                      | -0.8            | 51.32±7.92                 | -0.2            | 0.0001 | 0.06   | 0.0001         |
| Mental component<br>summary (MCS) | 52.2±8.28           | 45.22±12.94                     | -0.5            | 50.67±9.73                 | -0.2            | 0.0001 | 0.1    | 0.001          |

By paired t- test; P1 =before treatment Vs At 12thWeek of treatment; P2 =before treatment Vs At the end of Treatment; P3= at 12thWeek of treatment Vs At the end of Treatment; ES<sub>1</sub>= effect size baseline vs 12thWeek of treatment ES<sub>2</sub> = effect size baseline vs end of Treatment

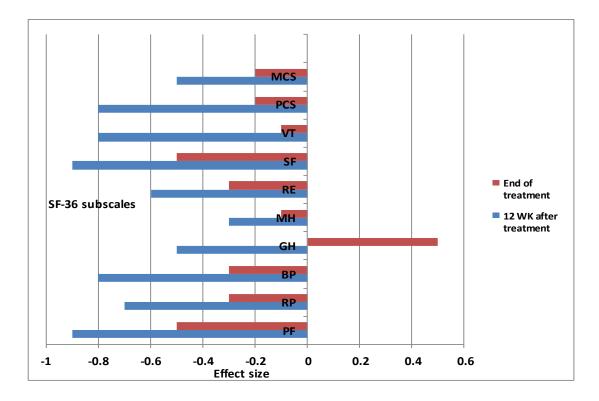


Figure 1: Effect sizes for SF-36 subscales at the 12th week of treatment and at the end of treatment among the studied chronic hepatitis C patients.

The study showed mean scores of the components of (SF-36) in CHC patients before treatment, and found that general health (GH) had the lowest score (66.41±15.75) followed by vitality (VT) (69.57±21.84). Many studies reported that CHC patients' showing significantly lower

SF-36 scores in six domains, especially in the VT, GH, and RP scales. 16-17. This is in agreement with Schwarzinger et al., 2004 who found that the studied Egyptian rural population did not find a significant reduction of HRQOL in patients chronically infected with

HCV compared with uninfected and this is contrary to previous Western studies which showed a consistent and marked reduction in health-related quality of life (HRQOL) in patients chronically infected with hepatitis C virus. <sup>18-20</sup> This may be explained by our patients characteristics as (60.8%) of patients had low viremia, (73.4%) had no other comorbidities, (43.3%) of patients' fibrosis stage was F1 with no F4 stage or advanced liver disease.

The study Also showed that physical component summery scores (PCS) slightly higher than mental component summery scores (MCS) (52.7±7.33) in CHC patients before treatment, and the reduction of mental components of HRQOL could be explained by patients awareness of their diagnosis have a more reduced HRQOL than those who are unaware.<sup>21</sup> In addition, patients with hepatitis C are stigmatized in society and the majority of the population of hepatitis C patients has a lower social economic status compared to the general population also evolving data now indicate that HCV itself may diminish HRQOL in the absence of advanced liver disease.<sup>22</sup> Perhaps as a result of extra hepatic symptoms related to HCV, cognitive dysfunction related to HCV, or a negative synergy between HCV and comorbid psychosocial disorders.<sup>23</sup>

HRQOL in CHC patients was significantly impaired in most SF-36 domains. Antiviral treatment impaired HRQOL of CHC subjects during early treatment (at the 12th week of treatment), and improved after stopping the treatment, this is in agreement with many previous studies with HCV patients.<sup>5,6</sup> The side effects of interferon with or without ribavirin, such as fatigue, malaise, flu-like symptoms, anemia, itching, skin rash or eruption, arthralgia, myalgia, depression, impaired sleeping quality, and loss of concentration, have been notable and have bothered CHC patients during antiviral treatment and affect HRQOL.<sup>24</sup> Previous reports from Western countries had focused on comparison of HRQOL before and after antiviral therapy in CHC patients, and they revealed that the HRQOL of CHC patients could be improved through antiviral therapy, and virological responders showed greater sustained improvement.<sup>25,26</sup> Our results for CHC patients were consistent with reports from Western countries. On the other hand, another study did not find any differences of the SF-36 scores in relation to the antiviral treatment.<sup>27</sup>

In our study, the effect sizes (ESs) were calculated which is simply a way of quantifying the size of the difference and quantified the effectiveness of interferon therapy and we found that the most affected dimensions at the 12th week of treatment were (PF, SF, VT and BP) (they were  $\geq\!0.8$ ) could be considered large change or deterioration, while mental health (MH) least affected (ES=-0.3) according to Cohen's criteria (0.20–0.49 considered small, values of 0.50–0.79 considered moderate, and values  $\geq\!0.80$  considered large). In addition, physical component scores more affected (ES=-0.8, large change) than mental component scores (ES=-0.5, moderate

change), But all dimensions improved by the end of treatment especially GH (ES=0.5) and VT (ES=-0.1). The large change or deterioration observed at the 12th week of treatment could be explained by the side effects of interferon and ribavirin. Moreover, the improvement observed in GH and VT was of great importance as both reflected the sense of wellbeing especially GH not only improved but also surpass the pretreatment value. The routine use of effect sizes, however, has generally been limited to meta-analysis - for combining and comparing estimates from different studies - and is all too rare in original reports of educational research. For this reason we did not find studies that were exactly similar to us, But we do it as one of the main advantages of using effect size is that when a particular experiment has been replicated, the different effect size estimates from each study can easily be combined to give an overall best estimate of the size of the effect. Studies measured the effect size in chronic hepatitis C patients all of these studies reported that sustained virological response is associated with improvements in quality of life in patients with or without advanced liver disease.<sup>28,29</sup> Thereby indicating that treatment of HCV may improve patientoriented outcomes and may be an important consideration in maximizing treatment adherence.

In conclusion, HRQOL in CHC patients was significantly impaired in most SF-36 domains during early interferon treatment (at the 12th week of treatment), and improved after stopping the treatment. Physical component scores more affected than mental component scores, but all dimensions improved by the end of treatment especially general health and vitality scores.

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Institutional Ethics Committee

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