Novelty Journals

ISSN 2394-7330

International Journal of Novel Research in Healthcare and Nursing
Vol. 4, Issue 2, pp: (237-249), Month: May - August 2017, Available at: www.noveltyjournals.com

# Quality of Life of Chronic Hepatitis C Patients Adherent to Sofobuvir Based Regimen

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***Abstract:*** **Chronic hepatitis C is a major cause of mortality and morbidity worldwide and has a negatively influence on quality of life. Sofosbuvir-containing regimens have been approved for treatment of hepatitis C virus that can have impact on the quality of life. Nurses play an essential role in the management, prevention, and care of people with HCV through educating patients with chronic hepatitis C infection and their families on preventing HCV transmission, disease process and potential treatment options .*The aim of the study* was to evaluate quality of life for chronic hepatitis C patients adherent to sofobuvir based regimen. A prospective observational *design* was used. The study was conducted at the viral hepatitis center which affiliated to Benha city. *A purposive sample* of 200 patients were chosen . *Two tools* were used for data collection; 1) Structured interviewing questionnaire to collect data about the patients' demographic characteristics, past and medical history. 2) The 36-item Short-Form Health Survey (SF-36) was used to evaluate quality of life for the studied patients.*The study results* showed that less than quarter (5.0,12.5,14.5, and 15.5) had good knowledge about Sofobuvir treatment as instructions, period of treatment, correct doses and side effect respectively these results were improved after implementing the program to reach 45.0,30.0,54.0 and 79.0 respectively, the results showed highly statistically significant differences through three phases,also *The study concluded that* quality of life of the patients was improved during follow up phase than base line before initiated the course of treatment and during the treatment regimen, also the patient knowledge was improved during the course of treatment and decline during follow-up phase but still better than pre-treatment phase with highly stastically significant diffrence between treatment phases. *The study recommended* that Disseminate health educational booklet for patients with hepatitis C virus undergoing Sofobuvir treatment related to quality of life and further studies about factors enhancing quality of life among hepatitis C virus patients undergoing Sofobuvir treatment is needed.**

***Keywords:*** **Quality of Life, Chronic, hepatitis C, Sofobuvir regimen, 36-item Short-Form Health Survey.**

## 1. INTRODUCTION

Chronic hepatitis C (CHC) is a major cause of mortality and morbidity worldwide. In particular, hepatitis C virus (HCV) infection not only has a negatively influence on patient-reported outcomes (PROs) but is also associated with major economic societal impact that includes direct and indirect costs as well as impairment in health-related quality of life (HRQL) and work productivity . [1, 2]

There are six known genotypes of HCV as the infection progresses to a chronic state in 80% of patients, whereas the virus clears completely after the acute infection in 20% of patients. It's transmitted through exposure to infected blood but sexual or vertical transmission is rare. The most common route of transmission, before blood donor testing was instituted in 1992, was through blood transfusions.. [3]

Chronic hepatitis C remains a considerable challenge in the Middle East region causing both a health and a financial burden. More efforts are required to highlight the problem and augment both prevention and treatment programmes. It affects over 185 million people, approximately 2–3% of the world's population. The prevalence is typically much higher

in Europe, prevalence peaks at 3.9–5.2% for those aged 55–64. Central and East Asia, which peaks at 8.8–8.9% for those aged 55–64 while Egypt has the highest prevalence rate of HCV in the world, making it the most challenging health problem facing the country. [4, 5]

An assessment of the degree of liver fibrosis with liver biopsy or noninvasive testing is necessary to determine the urgency of treatment. Treatment of patients with CHC infection should be considered based on prior treatment, extent of fibrosis or cirrhosis, genotype, potential adverse effects comorbidities. Early treatments of HCV can considerably decrease the risk of developing advanced liver disease such as cirrhosis and liver cancer. Antiviral therapies can eradicate the virus resulting in improvements in liver histology, which prevents liver-related mortality and thus reduce the related costs and improve health related quality of life (HRQL). [6, 7]

Quality of life (QOL) is a patient-reported measure comprised of, emotional well-being, physical and social functioning. It reflects on the perception of an individual regarding their health status. Health related quality of life focuses on the effects of a disease on every dimension of an individual's life including physical, social, psychological, emotional, and cognitive functioning. [8] Its assessment requires adapted and validated scale to measure different QOL domains. The 36-item Short-Form Health Survey (SF-36) is a multidimensional questionnaire that assesses eight different aspects of health. It is generic by nature which means that it opposed to disease-specific measures can be used to measure and compare outcomes across different diseases and treatments. This feature has made generic measures of health related quality of life increasingly popular among researchers and clinicians as it has become the most frequently used measure across a wide range of conditions. [9]

A pegylated interferon (peg-IFN)-based regimen has long been the standard treatment for patients with CHC. However, the complexity of peg-IFN and ribavirin regimen with its associated anemia, its substantial side effects and its drug-interaction profile limited the usefulness of those direct acting antiviral agents (DAAs) in clinical practice and excluded many patients from receiving treatment. [10] The treatment of CHC is rapidly improving .The new regimens are highly efficacious as it reduced the duration of treatment and have minimal side effects. [11, 12] Currently available interferon-free regimens are safer than previous regimens for patients with CHC, and they have also improved patient reported outcomes, such as health related quality of life (HRQL), fatigue, and work productivity. [13, 14]

In late 2014, single tablet regimen of Ledipasvir/sofosbuvir was approved by the United State Food and Drug Administration (FDA) for the treatment of genotype 1. It is commonly marketed under the brand name Sovaldi. For patients with genotype 2 HCV, 12 weeks of sofosbuvir and ribavirin (RBV) is indicated, this considering an overall sustained viral response (SVR) rate of 93%. [15]

Sovaldi is a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor indicated for the treatment of chronic hepatitis C (CHC) as antiviral treatment regimen. Its efficacy has been established in subjects with HCV genotype 1, 2, 3 or 4 infections, including those with hepatocellular carcinoma. Treatment regimen and duration are dependent on both viral genotype and patient population. It is currently approved as a once-daily, oral 400 mg tablet in combination with other agents for treating chronic HCV infection. Ledipasvir is an investigational drug that has shown picomolar potency against HCV genotypes. [16, 17]

The Egyptian government introduced sofosbuvir as the first DAAs into Egypt through the government funded National Treatment Program, which was administered either as a triple therapy in combination with peg-IFN and RBV or as a dual therapy combined only with ribavirin (for interferon non-eligible patients). As of July 2015, other treatment options, including an all DAAs therapy with simepravir and sofosbuvir were introduced. [18]

Nurses play an essential role in the management, prevention, and care of people with HCV through educating patients with CHC infection and their families on preventing HCV transmission, disease process and potential treatment options also vaccination against hepatitis A and B is recommended for susceptible patients with HCV infection. At every visit, patients being treated for HCV infection should be assessed by nurses for adherence to therapy and adverse effects, monitored for new or worsening psychiatric illness, and screened for alcohol and substance abuse. Baseline tests include complete blood count, creatinine level with glomerular filtration rate, aspartate and alanine transaminase levels; alkaline phosphatase levels and pregnancy testing in women of childbearing age should be measured. Quantitative HCV viral load is recommended at week 4 of treatment, and at 12 and 24 weeks after completion of therapy. [17] Determining treatment effectiveness is assessed by repeated measurement of HCV encoded RNA. Sustained viral response after cessation of treatment is associated with a 99% chance of being HCV RNA negative during long-term follow-up. [19]

During treatment, follow-up intervals need to be established on a case-by-case basis to optimize adherence, assess adverse events and potential drug–drug interactions, and monitor blood test results necessary for patient safety. All patients should be provided with contact details for a clinician to contact if problems arise in between appointments. Successful viral eradication is defined as undetectable plasma HCV RNA using a highly sensitive Polymerase chain reaction (PCR) assay 12 weeks after completion of DAAs therapy (SVR). Late relapse after SVR is very uncommon and the reappearance of HCV after this time is most frequently due to reinfection. [20] Despite the reported high efficacy and better safety profile of sofobuvir based regimen, the impact of these regimens on QOL remains unknown. Therefore, the aim of this study was evaluate quality of life of hepatitis C virus patients adherent to sofobuvir based regimen.

**Significance of the study:**

Hepatitis C virus (HCV) infection is a major cause of chronic liver disease and cirrhosis. The clinical impact of CHC is highly variable, from minimal changes to hepatocellular carcinoma, with or without extrahepatic manifestations. The outcome of CHC infection is not restricted to the clinical endpoints, as it affects health and psychosocial dimensions .In recent years, HCV infection has become increasingly noticeable. On the other hand, the development of highly effective antiviral therapy has enabled the actual treatment and cure of most diagnosed patients, but the burden from the most severe complications, such as hepatocellular carcinoma, keeps increasing. [21, 22]

World Health Organization reports that there are at least 185 million persons worldwide with the infection, causing 350,000 deaths annually. [17] Egypt, the single country with highest incidence of HCV infection in the world, has embarked on a government-sponsored mass treatment program using several combinations of DAAs. [23] Employees being treated for hepatitis C had high rates of absenteeism and impairment of their work productivity and QOL [24]

In Egypt, the prevalence rate of HCV infected individuals was 872,000 (15% of the population) in 2013, with an estimated incidence of newly infected 125,000 viremic individuals each year, the rate which is considered as one of the highest prevalence rates of HCV worldwide. [25]

**Aim of the study:**

This study aimed to evaluate the quality of life of chronic hepatitis C patients Adherent to Sofobuvir based Regimen through:

1-Assess quality of life of the patients before, during treatment and at follow up phase.

2-Assess patients' knowledge before, during treatment and at follow up phase after providing health educational guidelines

**Hypothesis:**

Quality of life of the patients will improved during follow up phase than before treatment and during the treatment regimen, also the patients' knowledge will improved after receiving health educational guidelines.

## 2. SUBJECTS AND METHODS

**Research design:** A prospective observational design was utilized to fulfill the aim of this study

**Setting:** The study was conducted at viral hepatitis center which affiliated to Benha city. This particular setting was chosen because it is the first specialized center at Qaluobia governorate for treatment of liver viruses since 2009. It institutes one of 42 specialized national treatment centres for treatment of viral hepatitis distributed throughout the country and provides medical services, investigations for free to all patients with viral hepatitis as hepatitis B clinic was opened at the center in February 2013. This institution serves patients from different governorates in Egypt and of various socioeconomic levels. The centre follow the same set of national guidelines for the treatment of patients with chronic HCV and are supervised by the National Committee for Control of Viral Hepatitis.

**Sample type and Criteria**: A purposive sample of 200 patients were recruited for the study using the following inclusion criteria; patients who were not eligible to receive peg-IFN (dual group) who receive daily Sofosbuvir (400 mg) plus weight-based RBV (1000 mg to < 75 kg or 1200 mg to >75 kg) for 24 weeks, patients aged 18 years or older, Eligible for

starting DAAs therapy, free from psychological disorders, free from other chronic diseases as hypertension and diabetes and willing to participate in the study. Patients who were eligible to receive Interferon (triple group) and treated with daily Sofosbuvir (400 mg) and weight-based RBV (1000 mg to < 75 kg or 1200 mg to >75 kg) plus weekly Peg-INF for 12 weeks is excluded from the study.

**Sample Size**: It was calculated based on the previous year census report of viral hepatitis center. The total number of patients who were not eligible to receive peg-IFN (dual group) was =400 patients (Viral Hepatitis Center Census, 2015). Sample size was calculated utilizing Yamane formula.

$$n = \frac{N}{1+N(e)2}$$

Where:

n= sample size

N= total population number (400).

e= margin error (0.05)

Sample size = 200 patients

**Tools of data collection**: Two tools were used for data collection:

**1-A structured interviewing questionnaire:**

It was designed by the researchers after reviewing related literature. It was written in Arabic language in the form of closed and open-ended questions. It encompassed two major parts:

**Part I:** Socio-demographic data of the studied patients such as; age, sex, marital status, educational level and monthly income.

**Part II:** Past and present medical history of the studied patients such as; duration of disease, discovering the disease and receiving interferon.

**Part III:** deals with patients' knowledge about chronic hepatitis C. It consisted of (2) sections;

*Section (1)* general knowledge regarding chronic hepatitis C, it consisted of (7) items (meaning of CHC, mode of transmission, signs and symptoms, complications, prevention, ideal healthy diet and methods of treatment).

*Section (2)* knowledge regarding treatment regimen of hepatitis C, it consisted of (5) items such as; (treatment instructions, period of treatment, correct doses, side effects and investigations before and after treatment)

**Scoring system of knowledge:**

Knowledge items were open-ended questions .The answers were classified into 3 categories (2) degrees for correct answer (1) degree for incomplete answer and (0) for incorrect or don't know answer. The total score for the knowledge of patients were calculated by the addition of the total score of all sections. The mean and standard deviation was calculated. Then, the score of total knowledge was divided into three levels, the patient was considered to have good level if the score was ≥75%, average level if the score was 50- < 75% and poor level if <50%.

**2- The 36-item Short-Form Health Survey (SF-36)**

This instrument is used to evaluate quality of life for patients before, during treatment and after three months of completing treatment. It is a generic scale to measure QoL. It is a multipurpose, short form health survey with only 36 questions it yields an 8-scale profile of functional health and well-being scores: Physical Functioning (PF), role limitations due to Physical Problems (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), role limitations due to emotional problems (RE), Mental Health (MH), and one single item scale on health transition. Scoring is a two-step process. First, numeric values are recoded per the scoring key given in **Table 1**. Note that all items are scored so that a high score defines a more favorable health state. In addition, each item is scored on a 0 to 100 range so that the lowest and highest possible scores are 0 and 100, respectively. Scores represent the percentage of

total possible score achieved. In step 2, items in the same scale are averaged together to create the 8 scale scores. **Table 2** lists the items averaged together to create each scale. Items that are left blank (missing data) are not taken into account when calculating the scale scores. Hence, scale scores represent the average for all items in the scale that the respondent answered. [26]

**Table 1: step 1: Recoding Items**

| Item numbers | Change original response category | To recoded value of: |
|---|---|---|
| 1, 2, 20, 22, 34, 36 | 1 → | 100 |
| | 2 → | 75 |
| | 3 → | 50 |
| | 4 → | 25 |
| | 5 → | 0 |
| 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 | 1→ | 0 |
| | 2 → | 50 |
| | 3 → | 100 |
| 13, 14, 15, 16, 17, 18, 19 | 1 → | 0 |
| | 2 → | 100 |
| 21, 23, 26, 27, 30 | 1→ | 100 |
| | 2 → | 80 |
| | 3 → | 60 |
| | 4 → | 40 |
| | 5 → | 20 |
| | 6 → | 0 |
| 24, 25, 28, 29, 31 | 1→ | 0 |
| | 2 → | 20 |
| | 3 → | 40 |
| | 4 → | 60 |
| | 5 → | 80 |
| | 6 → | 100 |
| 32, 33, 35 | 1 → | 0 |
| | 2 → | 25 |
| | 3 → | 50 |
| | 4 → | 75 |
| | 5 → | 100 |

**Table 2: step 2: Averaging Items to Form Scales**

| Scale | Number of items | After recoding per Table 1, average the following items |
|---|---|---|
| Physical functioning | 10 | 3 4 5 6 7 8 9 10 11 12 |
| Role limitations due to physical health | 4 | 13 14 15 16 |
| Role limitations due to emotional problems | 3 | 17 18 19 |
| Vitality | 4 | 23 27 29 31 |
| Emotional well-being | 5 | 24 25 26 28 30 |
| Social functioning | 2 | 20 32 |
| Bodily Pain | 2 | 21 22 |
| General health | 5 | 1 33 34 35 36 |

**Methods:**

He study was executed according to the following steps:

***1. Approvals:***

A written official approval to conduct this research was obtained from the National Committee for Control of Viral Hepatitis that was taken and delivered to the director of the viral hepatitis center, in order to obtain their agreement to conduct the study after explaining its purpose.

***2. Tools Validity:***

The validity of questionnaires were reviewed for content validity by a jury of five experts in the field of community health nursing at Ain shams university and Benha university to ascertain relevance and completeness of tools. Moreover, content, face and construct validity of the SF-36 questionnaire was evaluated. Correlations between each item and its hypothesized scale (item internal consistency) exceeded the criterion of 0.40 [27].

***3. Tools Reliability:***

The internal consistency of the SF-36 was assessed by Cronbach alpha coefficient. The Cronbach alpha was good (a=0.8). [28] Values equal or greater than 0.70 considered satisfactory.

***4. Ethical Considerations:***

Permission was obtained orally from each patient before conducting the interview and after giving a brief orientation to the purpose of the study. Confidentiality was ensured throughout the study process, and the nurses were assured that all data were used only for research purpose. No name was required on the forms to ensure anonymity. The participants were also informed about their right to withdraw at any time from the study without giving any reasons

***5. Pilot study:***

A pilot study was carried out on 10 % of the sample (20 patients) and were excluded from the study. The researcher informed all the studied sample about the aim, nature, process and expected outcomes from the study with the main purpose to test the relevance and applicability of the tools, detect any problem peculiar to the tools, determine the time needed to fill the study tools, and find out any problem that may interfere with the process of data collection. The pilot study revealed that statements of the questions were relevant.

***6. Procedures:***

The study was carried out from the beginning of January 2015 to the end of September 2015, covering a period of 9 months. The previous mentioned setting was visited by the researchers two days/week (Sunday and Wednesday) from 9.00 am to 12.00 pm according to the schedule of receiving treatment at viral hepatitis centre. The researchers reviewing patient's medical record, ensure health status, explained the aim of the study, and asked for participation. Upon consent to participate, patients were asked to fill the questionnaires. Average time for completion of questionnaires (20 - 25 minutes). The patients are interviewed at three time points as they fill the questionnaires: at baseline, before initiating therapy as the patient is provided with health educational guidelines about CHC and treatment regimen then interviewed the patient during 2 months of therapy and at the follow up phase after 3 months of completing their treatment and asked to fill the questionnaires as they come to the viral hepatitis centre for investigation and follow up . The number of assessed patients/week ranged from 5-10.

***7. Statistical analysis:***

Data analysis was performed using Statistical Package for Social Sciences (SPSS version 20.0) Descriptive statistics were used to describe characteristics of the study subjects (e. g. frequency, percentages, mean, and standard deviation). Test of significance (f test and chi-square test) was applied to test the differences between the groups. A statistically significant difference was considered at p-value $\leq .05$, and a highly statistically significant difference was considered at p-value $\leq .01$, while the p-value $>.05$ indicates non-significant results.

Novelty Journals

ISSN 2394-7330

International Journal of Novel Research in Healthcare and Nursing
Vol. 4, Issue 2, pp: (237-249), Month: May - August 2017, Available at: www.noveltyjournals.com

## 3. RESULTS

Table (1): Showed that 57.5% had aged more than 40 years with mean 43.6±11.3, 75.0% of them were male and 65.0% married. Regarding educational level 17.0% of them were university education and more and 59.0% had sufficient income.

Table (2): Showed that 58.5 % having the disease less than 5 years, 81.5% of them discovered the disease by feeling symptoms, and 69.5% receiving interferon therapy.

Figure (1): Illustrated that 43.5 % of the study sample had a family member receiving Sofobuvir treatment and the rest of the sample didn't had family member taking that treatment.

Table (3): Showed that there is improvement of patients' knowledge regarding CHC with highly statistically significant difference between patients' knowledge pre-treatment , during, and at follow-up phase.

Table (4): clarified that less than quarter (5.0, 12.5, 14.5, and 15.5) had good knowledge about Sofobuvir treatment as instructions, period of treatment, correct doses and side effect respectively. These results were improved after implementing the program to reach 45.0, 30.0, 54.0 and 79.0 respectively, the results showed highly statistically significant differences through three phases

Figure (2): Illustrated that 65.5% of the patients had good knowledge during follow-up phase, during treatment phase 62.5 % and pre-treatment 41.5%.

Table (5): revealed that quality of life during the follow up phase was improved than pre-treatment and during treatment regimen. The table also showed highly statistically significant difference between quality of life through treatment phases.

**Table (1): Frequency distribution of study sample according to their socio-demographic characteristics (n=200)**

| Socio-demographic characteristics | no | % |
|---|---|---|
| **Age** | | |
| <30 | 37 | 18.5 |
| 30- | 48 | 24.0 |
| 40- | 48 | 24.0 |
| 50+ | 67 | 33.5 |
| **X¯±SD** | 43.6±11.3 | |
| **Sex** | | |
| Female | 50 | 25.0 |
| Male | 150 | 75.0 |
| **Marital status** | | |
| Single | 21 | 10.5 |
| Married | 130 | 65.0 |
| widow | 49 | 24.5 |
| **Educational level** | | |
| Illiterate/read and write | 128 | 64.0 |
| Basic education | 18 | 9.0 |
| Secondary | 20 | 10.0 |
| University and more | 34 | 17.0 |
| **Income** | | |
| Insufficient | 52 | 26.0 |
| Sufficient | 118 | 59.0 |
| Sufficient and save | 30 | 15.0 |

Novelty Journals

ISSN 2394-7330

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**Table (2): Frequency distribution of studied sample according to their past and present medical history (n=200).**

| Medical history | No. | % |
|---|---|---|
| **Duration of the disease** | | |
| <5years | 117 | 58.5 |
| 5-10years | 50 | 25.0 |
| >10years | 33 | 16.5 |
| **Discovering disease** | | |
| During medical check-up | 37 | 18.5 |
| From the symptoms | 163 | 81.5 |
| **Receiving interferon** | | |
| No | 61 | 30.5 |
| Yes | 139 | 69.5 |

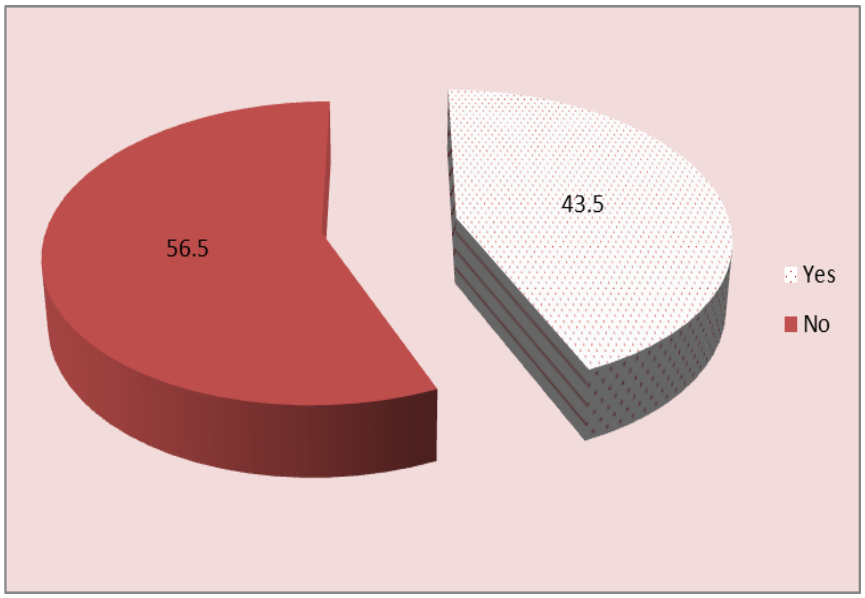


**Figure (1): frequency distribution of study sample regarding family member under Sofobuvir Based Regimen (n=200).**

**Table (3): Frequency distribution of study sample according to their general knowledge regarding CHC before, during and follow up Sofobuvir Based Regimen (n=200).**

| | Pre treatment % | | | During treatment % | | | Follow up phase % | | | $X^2$ | p-value |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Good | Average | Poor | Good | Average | Poor | Good | Average | Poor | | |
| **Meaning of CHC** | 4.5 | 9.5 | 86.0 | 15.0 | 51.5 | 33.5 | 16.5 | 52.5 | 31.0 | 15.8 | 0.000 |
| **Mode of transmission** | 24.0 | 58.5 | 17.5 | 57.5 | 31.5 | 11.0 | 59.5 | 30.0 | 10.5 | 64.2 | 0.000 |
| **Signs and symptoms** | 14.5 | 21.0 | 64.5 | 54.0 | 29.5 | 16.5 | 56.5 | 28.5 | 15.0 | 25.6 | 0.000 |
| **Complication of disease** | 51.5 | 29.0 | 19.5 | 99.0 | 0.5 | 0.5 | 55.5 | 26.5 | 18.0 | 19.0 | 0.001 |
| **Prevention of disease** | 71.0 | 22.0 | 7.0 | 89.0 | 0.5 | 10.5 | 72.5 | 20.5 | 7.0 | 47.35 | 0.000 |
| **Ideal healthy diet** | 95.5 | 0.0 | 4.5 | 62.0 | 34.0 | 4.0 | 63.5 | 32.5 | 4.0 | 86.12 | 0.000 |
| **Methods of treatment** | 72.0 | 27.5 | .5 | 85.5 | 5.0 | 9.5 | 85.5 | 6.5 | 8.0 | 67.19 | 0.000 |

Novelty Journals

ISSN 2394-7330

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**Table (4): Frequency distribution of study sample according to their knowledge regarding to Sofobuvir Based Regimen (n=200).**

| | Pre treatment % | | | During treatment % | | | Follow up phase % | | | $X^2$ | p-value |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Good | Average | Poor | Good | Average | Poor | Good | Average | Poor | | |
| **Treatment instruction** | 5.0 | 17.5 | 77.5 | 45.0 | 30.0 | 25.0 | 40.0 | 32.0 | 28.0 | 24.8 | 0.000 |
| **Period of treatment** | 12.5 | 25.0 | 62.5 | 30.0 | 51.5 | 19.5 | 22.5 | 46.5 | 31.0 | 64.2 | 0.000 |
| **Correct doses** | 14.5 | 21.0 | 64.5 | 54.0 | 29.5 | 16.5 | 56.5 | 28.5 | 15.0 | 55.6 | 0.000 |
| **Side effects** | 15.5 | 52.0 | 34.5 | 79.0 | 18.5 | 2.5 | 55.5 | 26.5 | 18.0 | 28.0 | 0.000 |
| **Investigation before/after treatment** | 10.0 | 40.0 | 50.0 | 55.5 | 34.5 | 20.0 | 55.0 | 35.0 | 10.0 | 46.7 | 0.000 |

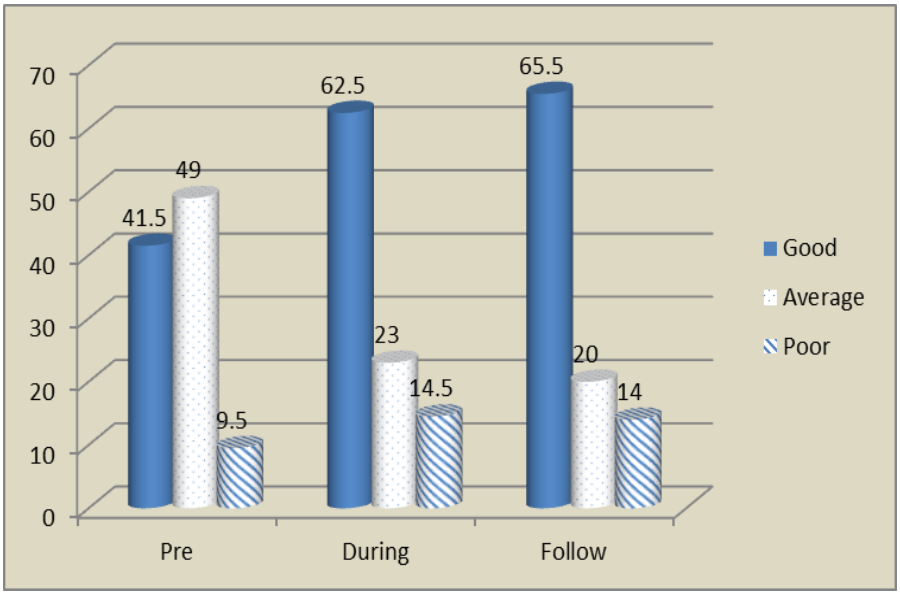


**Figure (2): frequency distribution of the study subjects according to their total knowledge scores (n=200).**

**Table (5): Quality of life mean scores of study sample through the treatment phases (n=200).**

| | Pre-treatment | During treatment | Follow-up phase | F test | p-value |
|---|---|---|---|---|---|
| | x-±SD | x-±SD | x-±SD | | |
| **Physical functioning (PF)** | 81.2±17.1 | 75.2±171 | 90.6±2.8 | 15.529 | 0.000 |
| **physical role limitations (RP)** | 64.5±24.8 | 57.5±24.8 | 82.5±24.8 | 70.638 | 0.000 |
| **Emotional role limitations (RE)** | 77.5±21.8 | 67.7±21.8 | 89.9±8.9 | 65.64 | 0.000 |
| **Vitality (VT)** | 62.3±15.2 | 56.8±20.8 | 97.0±2.0 | 112.64 | 0.000 |
| **Mental health (MH)** | 81.5±24.8 | 71.5±24.8 | 94.0±4.8 | 31.89 | 0.000 |
| **Social functioning (SF)** | 75.6±18.6 | 73.5±23.8 | 92.0±18.3 | 53.55 | 0.000 |
| **Bodily Pain (BP)** | 71.5±24.8 | 81.5±24.8 | 60.7±12.4 | 33.89 | 0.000 |
| **General health (GH)** | 51.6±32.4 | 48.5±22.1 | 79.0±15.9 | 42.85 | 0.000 |

## 4. DISCUSSION

Hepatitis C virus (HCV) infection is the main cause of liver disease and has a great impact on patient QOL. The estimate of chronically infected persons is about 160 million worldwide, but most of them are unaware of the disease. [20, 21] The results of this study will be discussed in frame of previously mentioned hypothesis.

Regarding socio-demographic data the present study revealed that more than half of the sample had aged more than 40 years with mean 43.6±11.3, three quarters of them were male and 65.0% married. This results in came accordance with **Metwally et al.** [29] who reported that the mean age of patients of their studied sample was 45.1±9.3, this may be due to that hepatitis C virus is a silent disease that it can't be discovered easily and **Rezik ,** [30] who found that more than two thirds of patients were male and the majority of the studied sample were married

In relation to educational level, the study revealed that less than one third of patients were university education and more and 59.0% had sufficient income. This finding is incongruent with **Ibrahim & Madian,** [31 who had studied" Impact of Hepatitis C on Health-Related Quality of Life in Egypt" and found that, more than half of the sample had high school level and university education or more.

As regards duration of disease, the present study revealed that, more than half of the studied sample had CHC less than five years, the majority of them discovered the disease by feeling symptoms, as well as around two thirds receiving interferon therapy. This finding agreed with **Rezik,** [30] who found that more than one half of the sample had chronic hepatitis C since one to less than five years. And **Hayat et al.** [32] who mentioned that most of patients with acute and chronic hepatitis C infection were a symptomatic. Also, more than half of patients had a family member receiving Sofobuvir treatment. This high percentage of infected members reflects that their knowledge was decreased about disease transmission and methods of disease control.

In relation to patients' knowledge regarding the disease, the study illustrated that there are improvement of patients 'general knowledge regarding CHC and treatment regimen during follow-up phase than pre treatment and during treatment with highly statistically significant difference between three phases. This goes in line with at least four other researches. *First*, **Mohsen et al.** [33]who had studied " Effect of Nursing Management Protocol on Selected Side Effects of Interferon and Ribavirin among Hepatitis C Patients" and found significance differences between knowledge of studied sample before the study and after 8 weeks regarding definition of viral hepatitis, action and side effects of medication, management of anorexia and fatigue also there was a highly statistical significance difference between patient's knowledge before and after 8 weeks related to signs and symptoms of hepatitis C virus, treatment and its dose, route and management. *Second*, **Hegazy et al.** [34] who had studied "The outcome of two teaching methods on creating awareness for hepatitis C Patients adherent to therapeutic regimen" and found that significant improvement in patients' knowledge was noticed in post and follow - up tests compared to pre – test in relation to therapeutic regimen. Moreover, the previously mentioned **Ibrahim & Madian,** [31] in his pre-test results that revealed that the great majority of the sample gave dissatisfied level of knowledge about HCV. *The fourth* **Shata,** [35] who found that patients' level of knowledge were in adequate level about concept of hepatitis C.

According to quality of life under Sofobuvir regmin the present study revealed that quality of life of the patients was improved during follow up phase than base line before initiated the course of treatment and during the treatment regimen. These results came in accordance with at least four researches. *The first*, **Youssef et al.** [36] who studied that "Health-related quality of Life in patients with chronic hepatitis C receiving Sofobuvir-based treatment, with and without Interferon" and found a significant change in HRQL across the three different time periods among patients receiving DAAs before, during and at the end of therapy. Moreover, **Youssef et al.** [37] found that HRQL improvement was progressive over time after the end of treatment, with scores after 24 weeks greater than at 12 weeks. *The third* **Youssef et al.** [38] found that patients achieved a sustained virologic response at 12 weeks after treatment reported significant improvement in their outcomes in interferon-free regimens. *The fourth* **Youssef & Henry** [39] in their study that revealed that interferon-free regimens containing sofosbuvir and ledipasvir have minimal negative effects on health-related quality of life during treatment. Thus, to improve QOL for CHC patients adherent to sofobuvir based regimen more attention should be made on educational intervention and increase patients awareness about CHC and new regimens of treatment.

## 5. CONCLUSION

Based on the results of the present study it can be concluded that, quality of life of the patients was improved during follow up phase than base line before initiated the course of treatment and during the treatment regimen, also the patients' knowledge was improved during the course of treatment and decline during follow-up phase but still better than pre-treatment phase with highly stastically significant diffrence between three phases.

International Journal of Novel Research in Healthcare and Nursing
Vol. 4, Issue 2, pp: (237-249), Month: May - August 2017, Available at: www.noveltyjournals.com

## 6. RECOMMENDATIONS

- Disseminate health education booklet and posters for patients with hepatitis C virus undergoing Sofobuvir treatment related to quality of life will be effective to increase patient knowledge about the disease and this treatment.
- Replication of the study on a larger sample and in different geographical areas in Egypt is recommended for generalization of findings.
- Further studies about factors that enhance quality of life among hepatitis C virus patients undergoing Sofobuvir treatment are needed.

## ACKNOWLEDGEMENTS

The authors would like to express their appreciation and gratitude to all patients who willingly participated in the study.

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