

Effect of Health Education Program on Life Style of Patients with Hepatitis C Virus Receiving Sovaldi Combination Therapy

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Abstract: Hepatitis C virus is currently the most common reason of chronic liver disease, including cirrhosis and hepatocellular carcinoma. Sovaldi combination therapy is one of the novel direct-acting antiviral drugs that intention different steps of the hepatitis C virus lifecycle, and an additional medication used to treat hepatitis C. **The aim:** Evaluate the effect of education program on life style of patients with hepatitis C viruses receiving Sovaldi combination therapy. **Sample:** Simple random samples composed of 58patients were included in this study. **Method:** Quasi experimental study was used. **Tools:** I. Interviewing Questionnaire: to assess demographic characteristics of the studied patients and patient's knowledge regarding hepatitis C viruses, life style and Sovaldi combination therapy. Patient's reported practices regarding life style, healthy nutrition during treatment, personal hygiene and medication administration. II. Patient's attitudes regarding Sovaldi combination therapy **Conclusion:** Application of the guiding program has a positive effect on patient's knowledge, life style and attitude regarding Sovaldi combination therapy. **Recommendations:** This study recommended that, provide safety precaution guides before start Sovaldi combination therapy through health education and Arabic brochures at outpatient clinics and hepatic centers to provide healthy life style measures regarding nutrition, physical activity, personal hygiene, drug administration.

Keywords: hepatitis C virus, life style, Sovaldi Combination Therapy.

1. INTRODUCTION

Hepatitis C viruses is one of Egypt's major health issues, and consequently, chronic hepatitis C virus (HCV) infection remains one of the most vital medical and community health issues facing recent medicine (*El Niwehy, et al, 2018*). Around the world, chronic hepatitis is estimated at 71 million people, over 95 percent of people with hepatitis C infection can be totally recovered within 2-3 months, 1.34 million people died of viral hepatitis in 2015, estimated 325 million people were living with chronic hepatitis infections globally, a significant number of people with chronic infection will developed cirrhosis or liver cancer in 2015 (*WHO, 2018*).

The National Treatment Program of the Ministry of Health ensured that Sovaldi (Sofosbuvir) became available in 2014 at prices appropriate to Egypt's economic situation (*Elgharably et al., 2016*). Sovaldi combination therapy, developed by Gilead Sciences (Gilead), the drug is a direct-acting antiviral agent and interferes with the HCV lifecycle and restraining viral replication (*European Commission Grants Marketing Authorization for Gilead's Sovaldi, 2014*).

Sovaldi combination therapy works by blocking one of the steps in the reproduction of the virus, it should be combined with other medications, which may consist of pegylated interferon (which stimulates the body's own immune reaction), ribavirin or other direct-acting antiviral that work in a different way (*Dolatimehr, et al,2017*).

Sovaldi combination therapy is usually well tolerated with no specific side-effects of its own; the mainly common side-effects observed in people taking Sofosbuvir with ribavirin or pegylated interferon are tiredness, headache, nausea and insomnia, depression, weakness, anemia and cause birth defects, so it should not be used by pregnant mother or their male partners (*European Association for the Study of the Liver, 2018*).

Sovaldi can interact with certain drugs including a number of tuberculosis medications, psychiatric treatment and herbal products containing St. John's Wort, for successful HCV treatment, there are a certain preparation and precaution that hepatitis C virus patient can do to improve their life style,(*Franciscus, 2015*).

Management of chronic hepatitis C concerning measures that may prevent further progression of liver disease and about accurate health-related behaviors such as nutrition or physical activity, patients with hepatitis C viruses should modify their lifestyle, adopting healthy behaviors that are necessary to improve health related condition in particular evidence of lifestyle influence on disease progression and effects. (*Scognamiglio, et al 2018*)

Patients with hepatitis C should avoid alcohol, maintain a healthy weight, and follow a diet, alcohol can lead to liver damage and patients with hepatitis C need to do all they can to minimize further injury to their livers, weight gain and eating foods high in sugar and fat can lead to a condition called fatty liver disease, which also can further damage the liver (*Leleu et al, 2015*)

Nurses play an important role in the management and care of patient with hepatitis C receiving Sovaldi combination therapy they : educate about the disease and its prevention; educate against behaviors, life style that increase the threat re-infection and spread to others; identify and address any adaptable risk factors and psychosocial factors; educate about treatment, nutrition ,medication personal hygiene and assess the patient desire for treatment; give the support during treatment; ensure referral to a specialist for hepatitis C; ensure monitoring for occurrence of complications; determine the patient need for support services; evaluate and facilitate resources and referral to support services (*Australasian Society for HIV, 2012*).

Significance:

InEgypt a low middle income country with one of the highest prevalence rates of hepatitis C in the world over the past 12 months, 200 000 people were treated and the cost of hepatitis C treatment for each individual dropped from US\$ 900 in 2014 to below US\$ 200 in 2016, Sovaldi can treat more than 95percent of people with hepatitis C infection, consequently reducing the possibility of death from liver cancer and cirrhosis, other than access to diagnosis and treatment is low, and it have less side effects than previously accessible therapy, and can totally cure the disease within three months (*W.H.O,2018*).

Prior to starting treatment of the Sovaldi combination therapy the patients' needs systematic plan for monitoring treatment; this monitoring should consist of a pre-treatment baseline estimation, consideration of drug-drug interactions, evaluation of treatment response and monitoring for their life style (*European Association for the Study of the Liver,2016*).

The aim of the study:

The current study evaluated the effect of health education program on life style of patient with hepatitis C viruses receiving Sovaldi combination therapy.

Research Hypothesis:

The current study hypothesized that; the application of health education program will be improving life style of patient with hepatitis C viruses receiving Sovaldi combination therapy.

2. SUBJECT AND METHODS

Research design:

In this study, quasi experimental study design was used.

Research Settings:

The study was carried out in the liver center outpatient clinics which affiliated to Ministry of Health, It is located in Banha, Qalyubiyah governorate, this center was chosen because it is the only center located in Qalyubiyah governorate for patients undergoing Sovaldi combination therapy.

Sample:

Purposive sample including the hepatitis c virus patients in the liver center in Banha, Qalyubiyah governorate, which composed of 58 patients from the liver center outpatient clinics, A pilot study was carried out for six patients included in the study sample, the sample were choice based on annual report of patient receiving Sovaldi combination therapy from 2014 to 2016 was 5800 and were chosen randomly from the previously mentioned settings according to the following:

Inclusive criteria:

Adult patients who were diagnosed with any type of genotype of hepatitis C viruses and receiving Sovaldi combination therapy that was available at the time of data collection.

Tools of data collection:-

Data were collected using the following tools:

I. Pre-designed Questionnaire Format by Interviewing: It was designed by the researchers based on updated related literatures to assess demographic characteristics and patient knowledge regarding life style and Sovaldi combination therapy it consisted of two parts:

Part I: Distribution of patient personal characteristics: It included age, level of education, income and occupation.

Part II: Patients knowledge regarding life Style, healthy nutrition during treatment, physical activity, and personal hygiene and Sovaldi combination therapy: it was modified from (*American Association for the Study of Liver Diseases, Infectious Diseases Society of America, International Antiviral Society (2016)*).

Scoring system:

According to the answers obtained from the patients was followed to evaluate their level of knowledge. The total score for the questionnaire was 13 grades (23 question) (equal 100%). their knowledge were categorized into; correct knowledge (scored 75% and more), and incorrect knowledge (scored less than 75%)

Part III: Questions regarding reported practices of their life style and Sovaldi combination Therapy: it was modified from **American Association for the Study of Liver Diseases, AASLD, (2016)**. It included 4 dimensions: their practices regarding drug administration, healthy nutrition during treatment, physical activity, and personal hygiene .Time needed for accomplish this tool is 10-15 minutes.

Scoring system:

Scoring system was done using three points ranging from 0 to 2 (Usually -sometimes- never) to measure patient reported practices regarding healthy nutrition, physical activity, personal hygiene and Sovaldi combination therapy. Practices score for each answer was given as follows :(2) grad to the practice (Usually) done (1) grade to practice (Sometimes) done and (0) grade for practices (Never) done. Total practices score was considered as satisfactory practices if the total scores $\geq 60\%$ and considered unsatisfactory if the score $< 60\%$.

II. Patients attitude:It included 5 dimensions: patient's attitude regarding (waiting time, doctor attitude, required investigation, getting the medication and care provided)(**likert scale, 2008**). Total attitudes score was considered as positive if the score $\geq 60\%$ and considered negative if the score $< 60\%$.

Content validity test:

The validity of the content was reviewed and determined by a pane of five expert professors in the Community Health Nursing Faculty of Nursing, Community Health Nursing Department, Ain Shams University after testing tools modifications were done to develop final form of study tools.

Administrative Design:

After explanation of the purpose of the study, the official permission was granted by a formal letter from the Dean of the Faculty of Nursing, Ain Shams University to the administrators of the previously mentioned settings. Also, a copy of study tools was given to them before data collection.

Ethical consideration:

An official permission was obtained. A clear and simple clarification about the aims and nature of the study was explained to all participant patients. Consent was obtained from the selected patient to ensure willingness to engage in the study. Patient participation was voluntary; they can withdraw at any time from the study. The researchers ensured confidentiality of the participant patient's personal data and the study hasn't any harmful effect on them.

Operational design:
Pilot Study

A pilot study was conducted for the purpose of testing the tools to determine the study's clarity, applicability, objectivity and feasibility to attain that, the tools were tested in the study sample in more than 6 patients (10% of the study sample) were included in the study sample.

Field work

- Actual field work was carried out in the period from the beginning January 2017 up to the end of June 2017, in the previously mentioned settings.
- Informed consent was secured before collecting data.
- For work organization, the researchers allocated 2 days each week (Tuesday and Thursday), from 8:30 AM –12 PM, 3- 4 patient / day, for data collection

Health education program construction:

This study was conducted in four phases, preparatory assessment, planning, implementation and evaluation phase.

First: Preparatory and assessment phase: Based on the results obtained from the pilot study, the guiding program was designed by the researchers also, it was revised and modified according to the related recent, national and international literature, and the various aspects of the research problem were taken into the considerations .The researchers collecting the following data according to previous tool.

Second: Development and implementation phase:

The development of the program based on patient assessment needs and the objective was developed.

General Objective:

At the end of health educations program the patient able to:

Improve their healthy life style regarding nutrition, physical activities personal hygiene Drug administration of Sovaldi therapy

The content:

- Function of liver.
- Hepatitis C viruses, causes, symptoms, mode of transmission and prevention.
- Life style of Patients with Hepatitis C:
 - Healthy nutrition regime during treatment with Sovaldi combination therapy.
 - Physical activities during treatment.
 - Steps of personal hygiene and hygienic measures to prevent recurrence of re- infection Steps of personal hygiene .
 - Meaning of Sovaldi combination therapy, duration of treatment,side effect, contraindication, follow up, investigation, types of treatment with Sovaldi combination therapy, mode of HCV transmission, symptoms, prevention from recurrence infection.

Teaching methods

Discussion, demonstration, re-demonstration and group discussion.

Media:

Suitable teaching aids prepared especially for the program were used such as, printed materials, posters, the guiding Arabic booklet and power point presentation & videos using laptop. A booklet was constructed for patients according to their educational level and needs assessment of the patient. It was prepared in simple Arabic language.

Third: Program implementation:

- The program was implemented over a period of 6 months; time allowed 6 hours distributed on 6 sessions: 2:45 hours for theory and 3:15 hours for practices. The time of every session was ranged from 35 minutes to 45 minutes.
- The actual work started by meeting the patients in the previously mentioned settings, first, the researcher introduced himself to the participant and gave them a brief idea of the study and its purpose.
- At the beginning of the first session, an orientation was done about the program, its purposes, and the patients were informed about the time of program sessions.
- Each session began with a summary of what was given through the new one's previous sessions and goals, considering the use of simple and clear language at all levels of the sample being studied.

Fourth: Program evaluation phase:

Evaluation was applied before and after the program through pre and posttest using the same study questionnaire, in order to appraise differences, similarities and areas of improvement, as well as defects and estimate the effect of health education program on patient's life style.

Statistical design:

By using the Statistical Package for Social Sciences (IBM SPSS) version 20, data were collected, organized, revised, coded, tabulated and analyzed the following statistical techniques were used: Numbers, percentages and mean value.

Significance of results

- When $P > 0.05$, it is statistically insignificant difference.
- When $P < 0.05$ it is statistically significant difference.

Significant difference:

- When $P < 0.01$ or $P < 0.001$ it is high statistically significant difference.

Part I: Distribution of Socio-demographic characteristics of the Patients with Hepatitis C Virus Receiving Sovaldi Combination Therapy (Table 1-2).
Table (1): Distribution of socio-demographic characteristics of the patient's (N=58).

Socio-demographic characteristics	N	%
Age in years		
20-30	3	5.6
31-40	8	13.7
41-50	11	18.7
51-60	36	62.1
Mean \pmSD	Mean \pmSD	
Sex		
Male	39	67.2
Female	19	32.8
Marital status		
Married	54	93.1
Not married	4	6.9
Residence		
Urban	21	36.2

Rural	37	63.8
Educational qualification		
Illiterate	14	24.1
Read and write	20	34.5
Preparatory	9	15.5
Secondary	10	17.2
University	5	8.6
Occupation		
Housewife	19	32.7
Governmental employee	21	36.2
Non-governmental employee	18	31.1
Income		
Enough	27	46.5
Not enough	31	53.4

Table (1): Shows that 62.1% of studied sample aged between 51-60 years old with the mean (35.23±11.58) years, 67.2% of them were males, while 93.1% of them were married and 63.8% was lived in rural areas. 34.5% of the patients with HCV were read and write 24.1% were illiterate, while 53.4% of them didn't have enough family income.

Table 2: Mean differences of patient's knowledge related to life style pre and post program (N=58).

Knowledge related life style	Knowledge score (max=100)				Mean Difference	Paired t-test	p-value
	Pre (n=58)		Post (n=58)				
	Mean ±SD	Median	Mean ±SD	Median			
Basic knowledge of hepatitis c virus	37.5±17.1	40.00	79.0±17.5	80.00	41.500	12.248	<0.001*
Basic knowledge of Sovaldi therapy	25.0±17.3	28.60	67.8±16.1	71.40	42.857	15.834	<0.001*
Diagnostic tests before, during and after treatment with sovaldi	45.9±15.0	45.50	76.8±12.7	81.80	30.90	11.532	<0.001*
Follow up during treatment of sovaldi	63.1±25.9	75.00	91.9±13.1	100.00	28.750	7.667	<0.001*
Nutrition during treatment with sovaldi therapy	42.5±30.2	33.30	76.7±25.3	66.70	34.167	7.050	<0.001*
Physical activity	40.8±25	38.71	86.7±17	54.6	55.4	7.601	<0.001*
Personal hygiene	23.6±25	54.60	63.3±25	31.8	32.9	8.640	<0.001*
Total knowledge	41.6±10.7	43.30	76.8±8.4	76.70	35.250	21.839	<0.001*

(*) Statistically significant at $p < 0.05$

Table (2): Shows that there was statistically significant difference between mean scores of patients regarding basic knowledge of life style and total knowledge, pre and post program implementation with (p- value <0.001).

The Effect of health education program on patient life style

Table 3: Mean differences of patient's life style pre and post program (N=58).

Reported Practices related life style	Practice score (max=100)				Mean Difference	Paired t-test	p-value
	Pre (n=58)		Post (n=58)				
	Mean ±SD	Median	Mean ±SD	Median			
Drug administration of Sovaldi therapy	76.3±13.8	75.00	78.1±14.1	75.00	1.875	1.778	0.083
Nutrition during treatment with Sovaldi therapy	72.1±14.8	66.70	75.4±16.4	66.70	3.333	1.778	0.073
Physical activity during treatment with Sovaldi	55.4±21.5	50.00	62.5±17.2	66.70	7.083	3.076	0.004*
Personal hygiene	54.4±25.2	50.00	65.6±22.4	62.50	11.250	4.767	<0.001**
Total life style	68.1±8.9	66.70	72.8±8.4	73.30	4.667	5.099	<0.001**

(*) Statistically significant at $p < 0.05$ (**) high statistically significant at $p < 0.001$

Table (3): Shows that there were statistically significant differences between mean scores of patient's life style pre and post program during treatment with Sovaldi (p. value:0.004). Also, there was high statistically significant difference between mean scores of patients life style pre and post program regarding patient's practices of personal hygiene and total practices with (p- value <0.001)

Table 4: Correlation between pre -post knowledge of patients and life style mean scores and their characteristics.

	Spearman's rank correlation coefficient		
	Scores (post-pre difference)		Satisfaction score
	Knowledge	Life style	
Knowledge		-.280	-.093
Life style	-.280		-.093
Age	.123	.197	-.044
Educational Qualification	-.004*	.085	-.075
Residence	-.088	.106	.020

(*) Statistically significant at $p < 0.05$

Table (4): Reveals that, there is statistically significant correlation between patients educational and their knowledge with ($p < 0.05$).

Table (5): Mean difference between patients attitude regarding life style during receiving Sovaldi combination therapy pre and post program (N=58)

Item	Pre-intervention		Post-intervention		T-test	P-value
	Mean	SD	Mean	SD		
Attitude	38.66	1.81	42.66	1.64	20.78	0.000*

* $p \leq 0.001$ high statistically significant

Table (5): Shows that, there is high statistically significant difference between mean score of patients' attitude related to Sovaldi therapy pre and post program.

3. DISCUSSION

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

The present study showed that more than half of patients aged 51-60 years with (35.23 ± 11.58) years; more than two thirds were males; while the most of them were married and more than two thirds were living in rural areas. This was supported by (Maaly, et al., 2016) who conducted a study about the effectiveness of nursing intervention program on emotional distress, self-efficacy and liver enzymes among hepatitis C Virus patients undergoing antiviral treatment (sovaldi medication) in the liver institute at Shebin-Elkom city he mentioned that the mean age of the HCV client was (39.5800 ± 16.57893) .

In contrast, this finding wasn't in agreement with (Eletreby et al., 2017) who conducted a study of Egyptian real - life experience of Sovaldi therapy efficacy and safety on chronic HCV genotype IV infected patients in Egypt; it was reported that the mean age of the HCV patient's was (53.55 ± 9.45) .

Considering residence more than two third of the studied group was living in rural areas. This result goes in line with (Kandeel et al, 2017) who was investigated prevalence of hepatitis C virus in Egypt it was revealed that, more than two thirds of the HCV patients were living in rural area.

Regarding education the present study clarified that more than one third of the studied subject were reading and writing, while less than quarter were illiterate, meanwhile more than half of them had not enough family income. These findings were in agreement with (Rezik, 2012) who conducted a study about assessing knowledge for patients with chronic hepatitis C receiving interferon therapy in Egypt; showed that, more than one quarter of studied patient were illiterate and only the minority of them had a university education.

However this finding was not in agreement with (Maaly, et al., 2016) who evaluated the effectiveness of nursing intervention program on emotional distress, self-efficacy, and liver enzymes among hepatitis C virus patients undergoing antiviral therapy in the liver institute at shebin-Elkom city; and mentioned that four fifths of the studied group were highly educated.

Regarding patients knowledge regarding life style mean scores pre and post program *Table (3)* the present study revealed that there was statistically significant differences between mean scores of patients regarding basic knowledge of hepatitis c virus and Sovaldi therapy and total knowledge pre and post program implementation with (p- value < 0.001). this was supported with (Leleu, et al., 2015) who studied Sofobuvir's cost effectiveness in treatment of patients with hepatitis C in France, and revealed that, there was a high statistically significant improvement of patients' knowledge about hepatitis C virus related causes and the methods of protection from hepatitis C virus (pre and post program implementation) also it was revealed that, there was a high statistically significant improvement of patients' it was revealed that, there was a high statistically significant improvement of patients' knowledge about antiviral therapy (Sovaldi) medication regarding its side effects and information's about dietary regimen pre and post program implementation.

Regarding patients life style practices mean scores pre and post program implementation *table (3)* the current study revealed that there was high statistically significant differences between mean scores of patient's practices pre and post program and patient total practices with (p value < 0.001). This study was supported by (AbdEl-Maksoud, et al., 2015) who evaluated the effect of nursing intervention to change the lifestyle of chronic hepatitis C patients in Egypt, it was revealed that nursing intervention was effective on all aspects of lifestyle for patients with chronic hepatitis C viruses and included the most significant aspects of healthy living for them as personal hygiene, lifestyle, sleeping pattern, nutritional behavior, exercise, excretion and Management of medication and getting knowledge regarding the hepatitis C diseases to maintain an excellent lifestyle.

Meanwhile this wasn't in agreement with (Rusu, et al., 2013), who investigated the effects of changes in lifestyle encompassing particular nutritional intervention and physical activity in the management of chronic hepatitis C patients

in Romania, revealed that intervention program had significant improvements in the liver function testes, while albumin and bilirubin levels were not significantly improved.

Also the current study revealed that there was statistically significant correlation between patient education and qualifications and their knowledge with ($p < 0.05$). **Table (4)** this result may be related to low educational level associated with decrease in knowledge among not read and write patients, and lead to absence of seeking behavior toward gaining information regarding newly hepatitis C treatment .

This result was in the same line with (*Abd El Rahman, 2018*) who investigated the knowledge, practice and satisfaction of patients with hepatitis C virus regarding Sovaldi therapy in Egypt, revealed that there was a statistical significant difference between total knowledge and educational qualification of the studied group with ($p < 0.05$), as the level of education has a significant effect on the clients 'level of knowledge;

Regarding patient's attitude related to life style during receiving Sovaldi combination therapy **table (4)** the current study revealed that there was high statistically significant difference between mean score of patient's attitude related to Sovaldi therapy (pre and post program intervention). This study suggested that increasing knowledge toward hepatitis C viruses and Sovaldi combination therapy may decrease individuals' negative attitudes towards Sovaldi therapy.

This result was supported by (*Maaly ,et al, 2016*), who revealed that there were statistical significant improvements of patients' emotional distress and self-efficacy post program implementation.

But this wasn't in agreement with (*Chen, et al., 2013*), who investigate knowledge and attitudes about hepatitis C virus (HCV) infection and its treatment in HCV mono-infected and HCV/HIV co-infected adults in the United States, and stated that one third of the studied group felt ashamed of having HCV and about one quarter of them felt that it was not important to treat HCV. Attitudes that reflected indifference and shame towards HCV were associated with lower scores of knowledge. Intervention studies are needed to effectively change attitudes to hepatitis C virus's and treatment.

According to research hypothesis the current study proved that the application of health education program were improved life style of patient with hepatitis C viruses receiving Sovaldi combination therapy.

4. CONCLUSION

Based on the study's results and research hypothesis, it was concluded that, more than two third of the studied group receiving Sovaldi therapy aged between 51-60 years old with the mean age (35.23 ± 11.58) years. More than one third of them were reading and writing, while less than quarter of them was illiterate. Statistically significant difference was found between mean scores of patients regarding basic knowledge related hepatitis C virus and life style and total knowledge pre and post program (p - value < 0.001). There was high statistically significant difference between mean scores of patients life style pre and post program regarding their total life style regarding nutrition ,physical activity ,personal hygiene, drug administration with (p - value < 0.001). There was statistically significant correlation between patient educational and their knowledge with ($p < 0.05$). High statistically significant difference was found between mean score of patients, attitude related to life style during receiving Sovaldi combination therapy pre and post program intervention.

5. RECOMMENDATIONS

According to these findings, the current study recommended the following:

1. Provide safety precaution guide before start Sovaldi combination therapy through health education session and simple Arabic brochures at outpatient clinics and hepatic centers which provide healthy life style measures regarding nutrition, physical activity, personal hygiene, drug administration.
2. Increase patients awareness regarding adverse reaction of Sovaldi combination therapy through health education classes provided by health care team specially the nurses and encourages the patient to change their life style.
3. Further studies on Further studies should be focused on studying the community health nurses roles to the implemented of follow up plane in different liver centers setting.

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