Impact of a designed supportive nursing program for hepatitis C patients on their functional health status during Interferon therapy in the National Hepatology Medicine Institute

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Abstract: Egypt has the largest epidemic of hepatitis C virus in the world. The World Health Organization estimated in 2011 that Egypt comes first worldwide in hepatitis C prevalence, with more than 22 % suffering from the disease. Little attention has been given to the neurobehavioral manifestations of the disease and the side effects of its antiviral treatment Interferon plus Ribavirin specially, depression. Depression increase the risk for patient noncompliance and a reason for discontinuation of antiviral therapy. The aim of the present study was to identify the impact of a designed supportive nursing program for hepatitis C patients on their functional health status during Interferon therapy. A quasi-experimental research design was used to achieve the purpose of the study. A sample of convenience of 50 adult male and female patients in the national hepatology medicine research institute and 6th of October health insurance hospital outpatient clinics. Patients were interviewed at treatment weeks 1, 16, 32, 48 and 72 weeks. Data pertinent to the study variables were collected through sort form-36(SF-36) health survey and pre/post knowledge assessment questionnaire developed by the researcher. Beck's Depression Inventory (BDI) to measure the severity of depression and a supportive nursing program for hepatitis C patients. In addition, a background data sheet was used to obtain information about the subjects pertinent to the study. The results revealed that side effects of Interferon begin a few hours after its administration and the patient develops tolerance in a few weeks with continuation of therapy. Patient education and monitoring are the cornerstones for enabling the patient to adhere to a therapeutic regimen. This study results recommend to improve hepatology nurse specialists skills of education, counseling and support to patients during antiviral therapy and teach patients self administering Interferon injections.

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1. Introduction

Egypt has the largest epidemic of hepatitis C virus (HCV) in the world. The World Health Organization estimated in 2011 that Egypt comes first worldwide in hepatitis C(HCV) prevalence, with more than 22 percent suffering from the disease and a

shocking yearly number of infections exceeding 165,000 (Deif, 2012). HCV transmission in Egypt is associated primarily with inadequate infection control during medical and dental care procedures (Paez *et al.*, 2010).



Figure 1: (Gobal HCV prevalence)

Chronic illness affects the entire family. Family life can be dramatically altered as a result of role reversals, unfilled roles, loss of income, time required to manage the illness, decreases in family socialization activities, and the costs of treatment. Stress and caretaker fatigue are common with severe chronic conditions, and the entire family rather than just the patient may need care(Ray& Streest, 2007). The high incidence of hepatitis C virus (HCV) makes it one of the greatest health threats facing the world today (Rhoads, 2003). Hepatitis C is a treatable disease, and over the last few years increasing numbers of patients have been offered antiviral treatment to eradicate the virus. However, treatment is cytotoxic and associated with a multitude of adverse side effects (Zucker& Miller, 2001).

Research indicates that individuals diagnosed with HCV have a relatively poor understanding of the disease (Stein *et al.*, 2001). This knowledge deficit has the potential to be highly detrimental because knowledge of HCV is associated with fewer high risk behaviors, greater self care behaviors, and enhance mood(Strauss& *et al.*, 2004).

Education is a critical component of any health care intervention, it has been found to improve treatment adherence, facilitate effective decision making, reduce health care costs, and improve health outcomes (Bourbeau *et al.*, 2004). A recent study found that participation in an HCV education class was associated with a significant increase in understanding of disease symptoms, transmission, and treatment, both immediately after the class and at follow up. This increase in knowledge has the potential to effect behavior change, enhance patient self- efficacy and in turn improve quality of life (Kizer *et al.*, 2006).

HCV research has been primarily biological in nature with the major focus on pharmacological treatment. Little attention has been given to the neurobehavioral manifestations of the disease and the side effects of its treatment, specifically, depression. Depression is a reported side effect of interferon alpha plus ribavirin, the antiviral therapy of choice in treating HCV. The most severe consequence of depression is suicide. Suicidal ideations, suicide attempts and successful suicides have been reported as adverse events of antiviral treatment regimens for HCV patients (Clark *et al.*, 2002).

Additionally, the reported fatigue and functional disability found to be were more strongly associated with depression severity than with severity of hepatic disease. The presence of depression may increase the risk for patient noncompliance with antiviral therapy and has been reported as a reason for discontinuation of therapy. Thus, leading to antiviral failure (Silberbogen *et al.*, 2005).

Treatment for HCV consists of a combination of pegylated interferon(IFN) and ribavirin (Manns *et al.*, 2001). Administered in a complex regimen of weekly subcutaneous injections and twice- daily oral medication. Ongoing monitoring is required through frequent medical appointments. Patients remain in this regimen for 12 months in order to achieve a sustained viral response

defined as having an undetectable viral load for at least 6 months post treatment(Crone & Gabriel, 2003).

Unfortunately, combination therapy with interferon and ribavirin has in addition to physiological side effects, there are also significant neuropsychiatric side effects including depression, anxiety, psychosis, suicidality, fatigue and impaired concentration (Kraus & *et al.*, 2003). In short, treatment for HCV is lengthy, rigorous and associated with side effects that are difficult to manage. Nurses have a critical role in the care of HCV co-infected patients who are undergoing treatment with interferon and Ribavirin. They both assess for treatment readiness prior to initiation and provide close monitoring for the development of neuropsychiatric disturbances while on therapy (Corcoran, 2009).

Significance of the study

Chronic viral C hepatitis and antiviral treatment are associated with nonspecific symptoms such as fatigue, irritability, nausea, anorexia, and headache. These symptoms have been directly associated with reduction of health related quality of life (HRQOL), as evidenced by reductions in functional health status, psychological status and general health perception measures (Davis *et al.*, 1994).

Raising patient's awareness of the potential side effects is very important in the approach to care, particularly in relation to compliance. In addition, providing information and advice to patients about how to manage their symptoms is essential(Grogan& Timmins, 2010).

Aim of the study

The aim of the study is to identify the impact of a designed supportive nursing program for hepatitis C patients on their functional health status during Interferon therapy.

Research Hypotheses

H1- Patient who will receive the designed supportive nursing program for Hepatitis C patients during Interferon therapy will have better functional health status.

H2- Patient who will receive the designed supportive nursing program for Hepatitis C patients during Interferon therapy will have more compliance and adherence to therapeutic regimens.

2. Subjects and Methods

Research design

A quasi-experimental research design was used to achieve the aim of the study.

Sample

A sample of convenience of 50 adult male & female patient in the National Hepatology Medicine research institute (25 patients) and 6th of October

health insurance hospital outpatient clinics(25 patients).

Inclusion criteria:

- Adult male and female patients diagnosed as hepatitis C patients and treated with Interferon therapy.

- Their age ranges between 20 and 60 years, not having liver cirrhosis.

- Patients who have seizure disorder and can not be controlled with anti- epileptic therapy were excluded.

- Patients free from cardiac irregularities.

- Patients did not suffer from depression.

- Patients have no autoimmune disease as rheumatoid arthritis or systemic lupus erythematosis.

. The patient participated for 18 months period.

Setting of the study

The study was conducted in the National Hepatology and tropical medicine research institute at 10 Kasr ElAini street and 6th of October health insurance hospital outpatient clinics in which the patients took their weekly dose of Interferon.

Ethical &legal considerations

Human subject approval was received from the board of the faculty of nursing at Cairo university as well as the administration of 6th of October health insurance hospital outpatient clinics& National Hepatology and Tropical Medicine Research Institute at 10 Kasr ElAini street. The agreement of Scientific Research Ethical Committee also was taken. Moreover, written permission (informed consent) for а participation was obtained from each participant at the first session after providing a complete description of the purpose& nature of the study. The right for self determination was preserved. All subjects were informed that their participation in this study is voluntary. Participants had the right to withdraw at any time.

Data collection tools:

Data pertinent to the study variables were collected through structured interviews, and the following tools were utilized to collect data:

- 1- A demographic data sheet questionnaire (consists of questions related to the age, sex, level of education, marital status, occupation, previous smoking, duration of disease, combination of interferon with other drug (Ribavirin tablets).
- 2- Short form- 36 (SF- 36) health survey: The SF-36 is a multi- purpose, short form health survey with only 36 questions. It is a valid and reliable instrument to measure all domains of the health status.

It is a questionnaire consisting of multi- item scales measuring 8 domains, four domains in the area of physical health (physical functioning, role disability, bodily pain, general health), and four domains in the area of mental health(vitality, social functioning, role disabilityemotional and mental health). Scale scores for these domains were derived by summing up the component items within each domain. The higher scores indicated better health than the lower scores. The scores of activities are 30 score, physical health scores are 20 score, psychological health problems are 15 score, bodily pain is 10 scores, energy and emotions are 45 score and mental health are 20 score.

3- Pre/post knowledge assessment questionnaire: This questionnaire developed by the researcher and consists of questions related to the Hepatitis C infection, hepatitis C transmission, prevention of HCV infection, how can hepatitis C affect the liver?, who should be treated with Interferon?, what is Interferon?, side effects most common during Interferon therapy, factors influencing completion of therapy with interferon, self injection of subcutaneous Interferon. The patient responds to the questionnaire as "complete" or "incomplete" answer. Scoring will done by the investigator for all subjects, every complete answer will take 1 score.

4- Beck's Depression Inventory(BDI):

It is a scale developed by Dr. Aaron T. Beck, is a 21 question multiple- choice self report inventory, one of the most widely used instruments for measuring the severity of depression.

This questionnaire is composed of items relating to symptoms of depression such as hopelessness and irritability, cognitions such as guilt or feelings of being punished, as well as physical symptoms such as fatigue and lack of interest in sex. The BDI is widely used as an assessment tool by health care professionals and researchers in a variety of settings. Each of the 21 items corresponding to a symptom of depression, there is a four point scale for each item ranging from 0 to3. Total score of 0-10 normal range, 11-16 mood swings, 17-20 on behave of depression, 21-30 is mild, 31-40 is severe and up to 40 is more severe depression(Beck, 2006).

5- Supportive nursing program for hepatitis C patients during Interferon therapy designed to clarify liver function, diagnostic tests, types of hepatitis, signs& symptoms of hepatitis, treatment of hepatitis C, Interferon, side effects of interferon, contraindication of Interferon and self injection of interferon. This program was in Arabic language and it's content based on patients needs and literature review and revised by 5 experts in the field of nursing.

Data Collection Procedure:

- (1) **Preparatory phase:**
- a- Receiving Approval: Once the permission was obtained to proceed with the study from the

concerned hospital authorities and agreement of the patients who were participated in the study, the investigator explained the purpose of the study to the patients, and collect the sociodemographic data for each patient and explained the other tools. All subjects provided written consent before participation.

b- Developing tools of data collection: all subjects were given socio- demographic, SF- 36 health survey questionnaire, Beck's depression inventory and all of them were given the knowledge assessment questionnaire to determine their own educational needs as well as their preferred time for attending the instructional program.

- Socio-demographic data sheet was developed to elicit subjects age, sex, level of education, marital status, duration of hepatitis C, combination of IFN with Ribavirin.

- SF-36 health survey questionnaire & Beck's depression inventory will be translated into Arabic & revised by experts in the nursing field. They were assessed at treatment weeks 1,16, 32, 48, and 72 weeks.

c- Pre/post knowledge questionnaire sheet: was assessed the knowledge of hepatitis C patients treated with Interferon: It consists of questions related to hepatitis C infection, transmission, prevention, how can hepatitis C affect the liver?, Interferon, who should be treated with Interferon, side effects of Interferon, factors affecting completion of Interferon therapy, teaching them the method of self injection of Interferon Alpha- 2b subcutaneous. It was assessed at treatment weeks 1, 48, and 72 weeks.

(2) Implementation phase:

- Conducting the supportive program: the supportive program constructed by the researcher and based on knowledge needs as expressed by patients. Knowledge about hepatitis C infection & Interferon treatment was developed by the investigator based on literature review and revised by experts in the nursing field.

- All subjects were interviewed five times, each time lasts 45- minute for each subject. All subjects administered SF-36 health survey questionnaire and Beck's depression inventory in the weeks: 1,16, 32, 48, and 72 week to follow their general health and severity of depression.

(3) Evaluation phase:

Knowledge level of patients was assessed again using the pre/post knowledge questionnaire sheet.

(4) Follow up phase:

All subjects were administered SF-36 health survey questionnaire, Beck's depression inventory and Pre/post knowledge questionnaire sheet in week 72 after completion of interferon treatment to identify the retained information and the reversion of interferon side effects. Data collection phase took 18 month from March 2011 to September 2012.

Pilot Study:

A Pilot study was conducted on 5 Hepatitis C patients undergoing Interferon therapy to test feasibility of the study as well as clarity and objectivity of the tools. And to determine the needed time to apply the study tools & to conduct the supportive program sessions. Limitations were determined & necessary modifications were considered to develop the final format. The pilot study sample as excluded from the main study sample.

Statistical analysis:

Data was analyzed, tabulated, computerized using SPSS program, relevant statistical tests were utilized. Numerical Data were expressed as mean and standard deviation. Qualitative data were expressed as frequency and percentage.

3. Results

The current study included 50 adult patients, (56%) were males and (44%) were females. As for age, it ranged from 20 to up to 50 years old: with a mean of 40.98±7.09, as regards marital status, the majority of the subjects were married (90%). The majority of the subjects were resident in urban areas (74%). In relation to educational level, (34%) of the subjects read and write and equal percentage have university education, while (32%) of the subjects have secondary school education. Additionally, the highest percentage of the subjects(44%) have professional work and (42%) of them have office work. The monthly income of the (84%) of the study subjects were enough for their daily requirements. As regards cigarette smoking, relatively highest percentage of the subjects were non smokers(66%).

The current study also revealed that, the majority of the subjects(60%) have been discovered the virus as a result of presence of symptoms, while the minority(40%) have been discovered it by chance. As regards symptoms, the highest percentage of the study subjects had ectrus(46%) and general weakness(40%), (94%) of the study subjects were taken interferon by the physician advice. All the study subjects took Ribavirin tablets with interferon and took the interferon injection in the hospital. The highest percentage(72%) of the study subjects did not know any other patients treated with interferon.

Table (1) revealed that, the general health condition among the study subjects in the week1 (72%) and week 16 (86%) was expressed by weak, but this percentage expressed by good among all the study subjects in the week 72. in relation to the health now compared with it since the last year, the majority

of the study subjects (92%) were seen that their health now was worse a little from last year in the week 1, but more than this percentage(98%) of the study subjects were seen that their health now was better a lot in the week 72 of the study.

Table (2) showed that, (86%) of the study subjects in week 48, the social relations affected by the therapy in a little way, but the majority of them(90%), the social relations did not affected at all in week 72. As regards social activity that affect visits, (74%) of the study subjects responded by few times in the week 32, while the majority of them (94%) responded by never happens in the week 72.

In relation to energy and emotions during the last four weeks, table(3) illustrated that, feeling of not energetic was the feeling of (90%) of the study subjects in week 72 who felt that most of the time. As regards feeling nervous and anger, (44%) of the study subjects in week 1 felt that most of the time, while at the end of the study (82%) of the study subjects in week 72 never felt nervous or anger. In relation to feeling down and nothing cheer you, (60%) of the study subjects in week 48 felt that most of the time and (52%) of the study subjects in the week 72 never felt nervous felt that. Regarding feeling no calm and no peace, (86%) of the study subjects felt that most of the time in the week 72, while (62%) of them felt that few times in the week 48.

Additionally, the same table revealed that, (94%) of the study subjects felt no power most of the time in week 48. In relation to feeling of depression, (48%) of the study subjects felt depressed in the week 48, while (70%) of them never felt that in week 72. As regards feeling of exhaustion, the highest percentage (68%) of the study subjects in week 16 always felt exhausted, while in week 72 (70%) of the subjects never felt exhausted. In relation to feeling of no happiness (78%) of the study subjects felt that most of the time in week 72. Regarding feeling of tired, (82%) of the study subjects in week 1 and 16 felt tired most of the time, while (54%) of them felt tired few times in week 72.

It is apparent from table(4) that, (80%) of the study subjects were knew interferon in week 48, but declined again in week 72 to (76%) who were knew that. As regards the hepatic patients who must use interferon, (88%) of the study subjects completely knew in week 72. In relation to the hepatic patients who must not use interferon, (88%) of the subjects knew the answer in the week 48 and also this percentage declined to (80%) only knew that after the completion of the therapy in the week 72.

As regards the action of interferon, only (12%) of the study subjects knew the answer in the week 1, (72%) of the subjects knew in the week 48, but also the percentage declined to (70%) in week

72who knew the action of interferon. In relation to HCV patients who benefit from interferon more than others, only (40%) of the subjects knew in the week 1, but, all of the subjects (100%) were gained the knowledge in the week 48 and 72. Regarding to side effects of interferon and ribavirin and to overcome this side effects, all the study subjects (100%) in the weeks 1,48, 72 knew the answers.

The same table also revealed that, only (40%) of the study subjects knew the factors that affect completion of interferon therapy in the week 1, but this percentage reached to (94%) of the study subjects knew this factors in the week 72. As regards self injection of interferon (26%) only of the study subjects knew how in the week 1, (80%) of them knew that in week 48, but this percentage declined to (68%) in the week 72. The mean of total scores of interferon in the week1, 48 and week 72 $was(4.46\pm1.12,$ 8.92 ± 0.82 and 8.76±1.07 respectively).

As shown in table(5), (80%) of the study subjects felt sad most of the time in week 48, while the majority (92%) of them in week 72 felt no sadness. In relation to pessimism, (88%) of the study subjects in week 48 lost hope a lot, while (98%) in week 72 did not loss hope. As regards past failure, (96%) of the study subjects in week 72 did not feel failure. Regarding loss of pleasure, (86%) of the study subjects in week 72 did not enjoy things as before. In relation to guilty feeling, all the study subjects in week 72 (100%) did not feel guilty.

Table(6) revealed that, the majority of the study subjects did not feel that they were being punished through the different weeks and all of them (100%) in week 72 also did not feel they were being punished. In relation to self- dislike, more than one third of the study subjects had loss of their self confidence in week 32(34%) and in week 48(44%), while, the majority of them (98%) in week 72 felt the same about their selves as ever. As regards selfcriticism, (84%) of the study subjects responded that they criticized their selves more than before in week 48, while(98%) of them in week 72 did not criticize themselves more than usual. In relation to suicidal thoughts and wishes, all the study subjects (100%) in all the study weeks had no thoughts of killing their selves. As regards crying, the majority of the study subjects in week 16 feel like crying, but they can not(62%) about one third of the subjects in week 48 crying more than usual, while, all the study subjects in week 72 replied that they did not cry more than usual. It is evident from table (7) that, all the study subjects (100%) in week 48 had slight change in sleeping pattern more than usual, while (56%) of them had no change in week 72. As regards irritability, (96%) of the study subjects in week 48

were more irritable than usual, but (64%) only in week 72 were not irritable more than usual. In relation to changes in appetite, (96%) of the study subjects in week 48 had a little change in appetite than usual, while (82%) of them in week 72 still had the same change in appetite.

Regarding to concentration difficulty, the same table illustrated that, (70%) of the study subjects in week 48 cannot concentrate as before, while (94%) of them in week 72 can concentrate as before. As regards tiredness and fatigue, all the study subjects (100%) in week 48 responded that they felt tired more easily than usual, while (70%) of them in week 72 felt not tired than usual. In relation to loss of interest in sex, (92%) of the study subjects had less interested in sex than before in week 48, while (90%) of them in week 72 had no change in sex interest than before.

Clearly, table (8) demonstrated that, the mean of the total depression scores in week 1 is $19.96\pm$ 3.82, the total scores 17-20 patient on behave of depression, the mean in week16 is 22.38 ± 3.96 , total scores 21-30 is mild depression, the mean in the week 32 and week 48 respectively are 17.54 ± 4.5 and 16.14 ± 1.85 , total scores 11-16 mood swings, and the mean in week 72 is 4.52 ± 2.39 , total score of 0-10

normal range. Table(9) revealed that, there is a significant correlation between the total scores of depression and total knowledge scores in week 1 with week 1(.375, which is significant at the 0.01 level), and week 32 with week 1(-.333, which is significant at the 0.05 level).

Table (10) showed that, there is a significant correlation between the total scores of short form health survey and total depression scores in week 1 with week 1(-.401, which is significant at the 0.01 level), week 1 with week 32(.332, which is significant at the 0.05 level), week 16 with week 16, 32, 48, 72(-.432, -.463, -.375 and -.537, which is significant at the 0.01 level), also, there is a significant difference between week 32 with week 1, 32, 72(.472, -.520, -.520, respectively which is significant at the 0.01 level) and a significant difference between week 32 with week16(-.330, which is significant at the 0.05 level), additionally, there is a significant difference between week 48 with week 48(-.431, which is significant at the 0.01 level) and a significant difference between week 48 with week 72(-.316, which is significant at the 0.05 level), finally, there is a significant difference between week 72 with week 72(-.470, which is significant at the 0.01 level).

Table (1): Frequency and percentage distribution of the study subjects as regards general health condition (n=50).

Variables	Week 1		Weel	k16	Weel	x 32	Wee	ek 48	We	eek 72
	No	%	No	%	No	%	No	%	No	%
General health condition:										
Weak	36	72	43	86	2	4				
Better	10	20	6	12	38	76	49	- 98		
Good	4	8	1	2	10	20	1	2	50	100
- Compared to last year, how do you see your health now:										
Worse much	2	4	6	12	2	4				
Worse a little	46	92	39	78	16	32				
The same	2	4	2	4	13	26	3	6		
Better a little			3	6	19	38	47	94	1	2
Better a lot									49	98

Table (2): Frequency and percentage distribution for the study subjects as regards effect of the therapy on social activities during the last four weeks(n=50).

Variables	Week 1		Weel	k16	We	ek 32	Week 48		Week 72	
	No	%	No	%	No	%	No	%	No	%
-Effect on social relations:										
Too much	5	10	4	8	2	4	-	-	-	-
Totally	18	36	20	40	5	10	-	-	-	-
With balance	12	24	16	32	15	30	7	14	-	-
A little	9	18	10	20	24	48	43	86	5	10
Not affect at all	6	12	-	-	4	8	-	-	45	90
-Effect on social visits:										
All the time	3	6	3	6	1	2	-	-	-	-
Most of the time	17	34	17	34	5	10	5	10	-	-
Sometimes	22	44	21	42	3	6	10	20	-	-
Few times	5	10	9	18	37	74	35	70	3	6
Never happens	3	6	-	-	4	8	-	-	47	94

Variables	Weel	k 1	Wee	k16	Week 32		We	Week 48		k 72
	No	%	No	%	No	%	No	%	No	%
-Feel not energetic:										
Always it happens	-	-	-	-	-	-	-	-	3	6
Most of the time	-	-	-	-	1	2	1	2	45	90
Sometimes	4	8	1	2	7	14	9	18	1	2
Few times	15	30	11	22	24	48	40	80	-	-
Never happens	31	62	38	76	18	36	-	-	1	2
-Feel nervous and anger:										
Always it happens	-	-	-	-	-	-	-	-	-	-
Most of the time	22	44	22	44	-	-	17	34	-	-
Sometimes	8	16	8	16	27	54	18	36	-	-
Few times	14	28	19	38	14	28	15	30	9	18
Never happens	6	12	1	2	9	18	-	-	41	82
-Feel down and nothing cheer you:										
Always it happens	2	4	1	2	-	-	-	-	1	2
Most of the time	16	32	16	32	4	8	30	60	-	-
Sometimes	18	36	21	42	21	42	15	30	1	2
Few times	12	24	12	24	21	42	5	10	22	44
Never happens	2	4	-	-	4	8	-	-	26	52
-Feel not calm and no peace:										
Always it happens	2	4	2	4	2	4	-	-	1	2
Most of the time	2	4	1	2	3	6	6	12	43	86
Sometimes	18	36	17	34	14	28	13	26	5	10
Few times	26	52	28	56	29	58	31	62	1	2
Never happens	2	4	2	4	2	4	-	-	-	-
-You feel no power:										
Always it happens	1	2	-	-	-	-	-	-	1	2
Most of the time	1	2	-	-	1	2	-	-	47	94
Sometimes	4	8	2	4	8	16	5	10	1	2
Few times	24	48	27	54	28	56	43	86	1	2
Never happens	20	40	21	42	13	26	2	4	-	-
- Feel of depression:										
Always it happens	2	4	3	6	-	-	-	-	-	-
Most of the time	21	42	19	38	7	14	24	48	-	-
Sometimes	18	36	20	40	23	46	21	42	2	4
Few times	6	12	5	10	17	34	5	10	13	26
Never happens	3	6	3	6	3	6	-	-	35	70

Table(3): Frequency and percentage	distribution	for the	study	subjects	as	regards	energy	and	emotions
during the last four weeks(n=50).									

Table(3) cont'd: Frequency and percentage distribution for the study subjects as regards energy and emotions during the last four weeks(n=50).

Variables	Week 1		Weel	k16	We	eek 32	We	ek 48	Wee	ek 72
	No	%	No	%	No	%	No	%	No	%
-Feel exhausted:										
Always it happens	32	64	34	68	21	42	6	12	-	-
Most of the time	18	36	16	32	19	38	30	60	-	-
Sometimes	-	-	-	-	8	16	13	26	2	4
Few times	-	-	-	-	2	4	1	2	28	56
Never happens	-	-	-	-	-	-	-	-	20	40
-Feel no happiness:										
Always it happens	-	-	-	-	-	-	-	-	-	-
Most of the time	1	2	-	-	2	4	1	2	39	78
Sometimes	25	50	22	44	28	56	29	58	9	18
Few times	23	46	28	56	20	40	20	40	2	4
Never happens	1	2	-	-	-	-	-	-	-	-
-Feel tired:										
Always it happens	5	10	7	14	3	6	1	2	-	-
Most of the time	41	82	41	82	34	68	21	42	3	6
Sometimes	4	8	2	4	10	20	24	48	-	-
Few times	-	-	-	-	3	6	4	8	27	54
Never happens	-	-	-	-	-	-	-	-	20	40

Table(4): Frequency and percentage distribution for the complete answer among knowledge related to Interferon for the study subjects (n=50).

Variables	Week 1		We	eek 48	Wee	k 72
	No	%	No	%	No	%
-Interferon is:	-	-	40	80	38	76
-Hepatic patients who must use interferon:	6	12	40	80	44	88
-Hepatic patients must not use interferon:	8	16	44	88	40	80
-Action of interferon:	6	12	36	72	35	70
-HCV patients benefit from interferon more than others:	20	40	50	100	50	100
-Side effects of Interferon injection:	50	100	50	100	50	100
-Side effects of Ribavirin:	50	100	50	100	50	100
-To overcome the side effects of interferon:	50	100	50	100	50	100
-Factors affect completion of interferon therapy:	20	40	46	92	47	94
-Self injection of interferon:	13	26	40	80	34	68
X [±] SD		6±1.12	8.92	2±0.82	8.76=	±1.07

Table(5): Frequency and percentage distribution of the study subjects as regards feeling sad, pessimism, past failure, loss of pleasure and guilty feelings(n=50).

	We	eek 1	Weel	k16	We	eek 32	We	ek 48	Wee	k 72
Variables	No	%	No	%	No	%	No	%	No	%
-Sadness:										
No sadness	5	10	-	-	7	14	-	-	46	92
Sad most of the time	28	56	31	62	34	68	40	80	3	6
Always sad	16	32	18	36	9	18	9	18	1	2
Can not tolerate sadness	1	2	1	2	-	-	1	2	-	-
-Pessimism:										
Not loss hope	13	26	4	8	18	36	5	10	49	98
Loss hope a lot	36	72	46	92	32	64	44	88	1	2
Not expect good things	1	2	-	-	-	-	1	2	-	-
-Past failure:										
Not feel failure	36	72	36	72	40	80	40	80	48	96
Failed more than expected	13	26	13	26	10	20	10	20	2	4
A lot of failure	1	2	1	2	-	-	-	-	-	-
-Loss of pleasure:										
Feel a lot of happiness	-	-	-	-	1	2	-	-	7	14
Not as before	45	90	42	84	35	70	47	94	43	86
Happy a little	5	10	6	12	12	24	3	6	-	-
Can not feel happiness	-	-	2	4	2	4	-	-	-	-
-Guilty feeling:										
Do not feel guilty	44	88	43	86	43	86	44	88	50	100
Feel guilty for most things	5	10	6	12	7	14	6	12	-	-
Feel guilty most of the time	1	2	1	2	-	-	-	-	-	-

Table(6): Frequency and percentage distribution of the study subjects as regards punishment feeling, self-dislike, self-criticism, suicidal thoughts or wishes and crying(n=50).

	Week 1		Wee	k16	We	eek 32	We	ek 48	Wee	k 72
Variables	No	%	No	%	No	%	No	%	No	%
-Punishment feeling:										
Not feel punished	38	76	43	86	49	98	47	94	50	100
Maybe punished	12	24	7	14	1	2	3	6	-	-
-Self- dislike:										
Feel the same about myself	26	52	23	46	26	52	28	56	49	98
Loss of self confidence.	11	22	12	24	17	34	22	44	1	2
Feel disappointed	13	26	15	30	7	14	-	-	-	-
-Self- criticism:										
Not criticize myself	16	32	16	32	19	38	8	16	49	98
Criticize more than before.	30	60	28	56	29	58	42	84	1	2
Criticize for all of my faults.	3	6	4	8	-	-	-	-	-	-
Blame for everything bad that happens.	1	2	2	4	2	4	-	-	-	-
-Suicidal thoughts or wishes:										
No thoughts of killing myself.	50	100	50	100	50	100	50	100	50	100
-Crying :										
Not cry more than used	12	24	8	16	19	38	8	16	50	100
Cry more than usual.	11	22	9	18	9	18	18	36	-	-
Cry over every little thing	3	6	2	4	4	8	1	2	-	-
Feel like crying, but can not	24	48	31	62	18	36	23	46	-	-

Table(7): Frequency and percentage distribution for the study subjects as regards change in sleeping pattern,
irritability, changes in appetite, concentration difficulty, tiredness or fatigue and loss of interest in sex(n=50).

	We	ek 1	Wee	k16	We	ek 32	We	ek 48	Wee	k 72
Variables	No	%	No	%	No	%	No	%	No	%
-Changes in sleeping pattern:										
No change in sleep.	-	-	-	-	-	-	-	-	28	56
Sleep slightly more than before.	22	44	7	14	29	58	50	100	21	42
Sleep more than usual	27	54	40	80	17	34	-	-	1	2
Sleep most of the day.	1	2	3	6	4	8	-	-	-	-
-Irritability:										
Not more than usual	-	-	-	-	2	4	-	-	32	64
More than usual	30	60	28	56	40	80	48	96	18	36
Much more than usual	19	38	21	42	6	12	2	4	-	-
All the time	1	2	1	2	2	4	-	-	-	-
-Change in appetite:										
No change in appetite	1	2	-	-	-	-	-	-	7	14
Little change than before	9	18	6	12	22	44	48	96	41	82
Much change than before	37	74	36	74	18	36	2	4	2	4
No appetite at all.	3	6	8	16	10	20	-	-	-	-
-Concentration difficulty:										
Can concentrate as before.	3	6	1	2	7	14	15	30	47	94
Not concentrate as before	32	64	31	62	32	64	35	70	2	4
Not concentrate for long time	15	30	16	32	10	20	-	-	1	2
Not concentrate completely	-	-	2	4	1	2	-	-	-	-
-Tiredness or fatigue:										
Not tired than usual	-	-	-	-	1	2	-	-	35	70
More easily than usual	33	66	28	56	38	76	50	100	15	30
More tired than before	17	34	21	42	9	18	-	-	-	-
Much more than before	-	-	1	2	2	4	-	-	-	-
-Loss of interest in sex:										
No change than before	5	10	1	2	4	8	3	6	45	90
Less interested than before	43	86	45	90	41	82	46	92	4	8
Much less interested now	2	4	3	6	4	8	1	2	1	2
Lost interest completely	-	-	1	2	1	2	-	-	-	-

Table(8): Frequency and percentage distribution for the study subjects as regards total depression scores(n=50).

	We	ek 1	Week16		We	ek 32	Week 48		Week 72	
Ranges	No	%	No	%	No	%	No	%	No	%
1-	-	-	-	-	-	-	-	-	49	98
11-	10	20	3	6	23	46	23	46	1	2
17-	15	30	11	22	18	36	27	54	-	-
21-	25	50	35	70	8	16	-	-	-	-
31-	-	-	1	2	1	2	-	-	-	-
40-	-	-	-	-	-	-	-	-	-	-
X [±] SD	19.96	± 3.82	22.38±	= 3.96	17.5	54± 4.5	16.14	4±1.85	4.52=	= 2.39

Table(9): Correlations between total scores of depression sheet and total knowledge scores as regards the study weeks(n=50).

Correlations	Total knowledge score	Total knowledge score	Total knowledge score
	Week 1	Week 48	Week 72
Total score of depression. Week 1	.375**	.115	172
	.007	.426	232
Total score of depression. Week 16	151	148	023
	.295	.304	.873
Total score of depression. Week 32	333*	145	.026
	.018	.316	.857
Total score of depression. Week 48	.171	174	122
	.234	.226	.398
Total score of depression. Week 72	235	205	.073
	.101	.153	.616

*Correlation is significant at the 0.05 level(2-tailed).

** Correlation is significant at the 0.01 level(2-tailed).

Correlations	Total depression				
	score	score	score	score	score
	Week 1	Week 16	Week 32	Week 48	Week 72
Total score of short form.	401**	.035	.332*	.027	.255
Week 1	.004	.810	.018	.851	.074
Total score of short form.	.256	432**	463**	375**	537**
Week 16	.072	.002	.001	.007	.000
Total score of short form.	.472**	330*	520**	268	520**
Week 32	.001	.019	.000	.059	.000
Total score of short form.	.093	248	058	431**	316*
Week 48	.519	.082	.687	.002	.026
Total score of short form.	.162	087	122	105	470**
Week 72	.262	.547	.399	.468	.001

Table(10): Correlations between total scores of short form health survey and total depression sheet scores as regards the study weeks(n=50).

*Correlation is significant at the 0.05 level(2-tailed).

****** Correlation is significant at the 0.01 level(2-tailed)

4. Discussion

As regards socio-demographic characteristics, the study revealed that more than one half of the studied subjects were males. This findings is congruent with the study conducted by (Sobhonslidsuk *et al.* (2006), who found that the majority of their study sample were males. In general, females have more health concerns and are more treatment-seeker than males.

In relation to age, the majority of the participants were in their thirties to up to forty years. In the former study conducted by Sobhonslidsuk *et al.* (2006), who stated that the elderly is associated with less favorable appraisal of personal health due to their health concerns, pessimistic health appraisals, social isolation and unemployment. In a similar study done by McHutchison *et al.* (2009) about peg-interferon alfa-2b or alfa-2a with ribavirin for treatment of hepatitis C infection stated that factors associated with non-virological response are high baseline HCV viral load, high fibrosis stage in the liver, old age, male gender, obesity, alcohol intake and liver steatosis.

Regarding marital status, the present study revealed that the majority of the study sample was married. Chong *et al.* (2003) eported that marital status did not affect health related quality of life (HRQL), so chronic liver disease (CLD) patients could get psychosocial support from other family members even when they are single or divorced. The former study conducted by Sobhonslidsuk *et al.* (2006) goes on line with the results of the study done by Hsu, *et al.* (2009) that revealed that married couple had more psychosocial and emotional support than single, unmarried or divorced people.

In relation to place of residence, the majority of the study subjects were resident in urban areas (Table 1). An estimated 6 million Egyptians had chronic HCV infection in 2008, prevalence of chronic HCV infection in Egypt is higher among men than women, increases with age and is higher among persons residing in rural versus urban areas (El-Zanaty& Way, 2008). From the researcher point of view, most of Egyptians have roots of rural areas and came from it for work and education.

Regarding to educational level, equal percentage of the study subjects read and write and have university education and the highest percentage of the subjects were work in a professional work. Education can help people cope their own problems. Low educated people are prone to have psychological problems and have false beliefs. Lower educational level and type of career reduced vitality and role emotion (Sobhonslidsuk *et al.*, 2006). In relation to the monthly income of the study sample, the majority of them stated that their monthly income was enough. This study findings is consistent with that of a study done by Schwarzinger *et al.* (2004), which revealed that people with lower socioeconomic status have more stress and more depression.

The presence of financial burden can lower HRQL. The estimated cost of the care and treatment program for the Egyptian government is \$80 million annually, which covers 40% of total costs of the program; the remaining 60% is paid by insurance companies and patients. Market competition has driven down the price of medications for a standard 48-week course of treatment; since program inception, medication costs have decreased from approximately \$12,000 to < \$2,000. Nevertheless, treatment costs remain a barrier, hampering efforts to reach a greater proportion of HCV infected persons (Ford *et al*, 2012).

As regards cigarette smoking, the highest percentage of the subjects in the present study were non smokers. Smoking may lead to more rapid progression of HCV infection, including hepatic fibrosis. Importantly, smokers may also have a lower response rate to interferon(IFN) therapy, non smoker patients had a better sustained virological response rate compared to smoker patients (ElZayadi *et al.*, 2004). Finally, not only does cigarette smoking negatively affect liver function risk for liver cancer, and over all health, but it has also been associated with reduced quality of life in HCV positive patients (Balfour *et al.*, 2006). Cigarette smoking may induce immune impairment and counteracting interferon effect. It was shown that tobacco smoking had a suppressive effect on human immunity as a result of decreased serum concentration of immune-globulins (ElZayadi, *et al.*2004).

Considering discovery of the HC Virus, results of the present study revealed that the majority of the study subjects have been discovered the virus as a result of presence of symptoms. The highest percentage of this symptoms were ectrus and general weakness. In a study done by Silberbogen, et al, (2009), who stated that symptoms of HCV can include fatigue, weakness, general malaise, mild abdominal pain, chronic pain, and loss of appetite, although some patients may not experience any identifiable symptoms. HCV patients should know that, if you wait to have symptoms of hepatitis C before you start treatment, your liver may already be severely damaged. Symptoms that may be related to chronic hepatitis C include, fatigue flu-like symptoms, as fever, chills, muscle aches, joint pain, and headaches, nausea, unexplained weight loss, psychological disorders including depression. tenderness in the abdomen and jaundice(Genentech, 2010).

As regards general health condition, the present study revealed that the highest percentage of the study subjects in (week 1) and (week 16) felt that their general health condition was weak (table1). In relation to the (week 72) when there is successful interferon therapy and sustained virological response. all the study subjects had good general health condition and their health was better a lot when compared to the last year in the majority of them. These findings were consistent with Hauser et al (2004) study findings about the biopsychosocial predictors of health related quality of life in patients with chronic hepatitis C, which revealed that, the reduced over all HROOL in patients with chronic hepatitis C could be best predicted by disease-related worries and psychiatric and active medical comorbidities and not by the severity of the liver disease or sociodemographic factors such as age. With increasing emphasis on the patient as the focal point of health care, preservation of patient functioning and well-being is viewed as the principal goal of medical care and is best evaluated by the patient.

Considering the effect of the interferon therapy on social activities during the last four weeks

of treatment(Table 2) showed that, the highest percentage of the study subjects the social relations with family, friends, and neighbors were affected totally in (week 1) and (week 16) and did not affected at all in week 72. also, the family and friends visit affected in few times of in the majority of the study subjects in (week 32)of the therapy while, it was never affected in the majority in week 72 after completion of antiviral treatment. In a similar studies done by Richmond et al. (2007) research has found that over 50% of patients with HCV have experienced discrimination in a variety of contexts, resulting in alienation from co-workers, family, friends, and even medical providers, at time when they are in great need of support. The experience of treatment has been associated with negative psychological outcomes, including depression, anxiety, poorer work adjustment, greater difficulty accepting one's illness, increased pessimism and a sense of loss of control. Patients may isolate themselves, thereby reducing their likelihood of receiving support from others (Golden et al, (2006). Hilsabeck et al.(2005) found that the most significant predictor of fatigue in patients with CHC was poor social functioning.

In relation to energy and emotions during the last four weeks of treatment, the findings in (Table 3) showed that, feeling not energetic was the feeling of the majority of the study subjects in (week 72) who felt that most of the time. The highest percentage of the subjects in week 1 felt nervous& anger most of the time, while the majority of them in week 72 never felt that. Also, the majority of the study subjects in week 48 felt down and nothing cheer them most of the time, while in the week 72 they never felt that. In relation to feeling no calm, no peace, and no power, the majority of the subjects in the current study felt that most of the time in the week 72 after 6 months of treatment completion. Regarding depression, the highest percentage in the week 48 were depressed while the majority of them never felt depressed in week 72.

The findings of the present study also revealed that the highest percentage of the subjects in week 16 always felt exhausted, the majority of them felt no happiness most of the time in week 72, also felt tired most of the time in week 1 and week 16. Consistent with the current study findings, Younossi, *et al* (2007) asserted that IFN regimens are associated with substantial side effects as flu-like symptoms, persistent or pervasive fatigue often begins with a fever and reluctance to participate in activities, mental laziness or absence of motivation. The association between HRQL and IFN treatment induced depression was examined in a study by Dan, *et al* (2006) similar to previous findings, HRQL measured using the SF- 36 and the CLDQ decreased during antiviral therapy in HCV- infected patients but then increased to or exceeded baseline levels within 24 weeks of therapy. They concluded that depression was the most consistent predictor of impaired HRQL in patients receiving IFN- based therapy for CHC.

As regards Interferon(Table 4), the whole sample stated that they did not know interferon in week 1, while in week 48 the majority of them were knew and gave a complete answer, but in week 72 the percentage was declined a little. In the current study, the majority of the study subjects in week 1 did not know the hepatic patients who must use and must not use interferon, in week 48 the majority of the subjects were knew patients who must use and must not use interferon, while in week 72, this percentage declined a little as regards the patients who must not use interferon(Table 5). Rifai, et al. (2006) stated that a pre-treatment psychological evaluation should assess for those factors that will maximize the likelihood of a successful treatment course. Therefore, clinicians should assess for knowledge and expectations about treatment for HCV, motivation and ability to adhere to treatment, and psychosocial support. After an assessment, clinicians can help prepare patients for treatment by providing education, establishing realistic expectations of treatment success.

As regards side effects of interferon and ribavirin and how to overcome this side effects, all the study subjects in weeks 1, 48, 72 knew the answer (Table 4). In relation to factors that affect complication of interferon therapy, more than half of the study subjects did not know what are this factors in week 1 while the majority of them knew the answer in the weeks 48 and 72. Regarding self injection of interferon, the majority of the study subjects did not know how to do it in week 1 and also the majority of them in week 48 knew how to inject themselves with interferon, but this percentage declined in week 72. In (2005), a study of different antiviral treatments on patients with hepatitis C by Kang and his colleagues showed that all treatment regimens had reduced the quality of life of patients in the primary stages of treatment and side effects had reduced their compliance and adherence to treatment, whereas, providing information to the patients about their treatment and its side effects will increase their tolerance, compliance, and adherence to antiviral therapy.

As regards feeling sad, the majority of the study subjects felt sad most of the time in week 48, while the majority of them in week 72 felt no sadness(Table 5). In relation to pessimism, the majority of the subjects in weeks(1, 16, 32, 48) lost hope a lot, while in the week 72 the majority of them stated that they did not loss hope(Table 5). Regarding

loss of pleasure, the majority of the study subjects in all the weeks(1, 16, 32, 48 and 72) did not feel happiness as before. As regards guilty feeling, the majority of the subjects in the four weeks (1, 16, 32, 48) and all of them in week 72 did not feel guilty (Table 5). Kobayashi, (2008) stated that most people are aware that the significant benefits on interferonbased therapy to treat chronic hepatitis C virus(HCV) may cause a variety of physical side effects. It is important to be aware that this treatment may also have emotional and mental health side effects. Approximately 20% to 30% of people undergoing interferon-based therapy for hepatitis C experience depression. By being aware of this possibility, you are more likely to recognize the symptoms early, request one of the many antidepressant medications available to treat it, and feel better for the remainder of the treatment period.

In relation to suicidal thoughts and wishes(table 6), all the study subjects in all the five weeks(1, 16, 32, 48 and 72) had no thoughts of killing their selves, from the researcher point of view, the religion and faith affect the Egyptian people and prevent them to think of suicide in order to not punished from the God. As regards crying, the majority of the study subjects in (week 16) feel like crying, but they cannot, about one third of the subjects in (week 48) crv more than usual, while, all of the study subjects in week 72, did not cry more than usual(Table 6). These findings are consistent with Otong (2003) who stated that clients must be assessed for suicidality initially and throughout treatment. Once a definitive diagnosis of IFN- alphainduced depression is established, pharmacological and psychotherapeutic interventions must be initiated.

As regards changes in sleeping pattern, the majority of the study subjects in (week 1) and (week 16) sleep more than usual(table 7), the majority of them in (week 32) and all of them in (week 48) sleep slightly more than before, while in week 72 more than half of the subjects had no change in sleep. In relation to irritability, the majority of the study subjects in the four weeks 1, 16, 32, 48 felt irritable more than usual, while the majority of the subjects in week 72 did not feel irritable more than usual(Table 7). Regarding to change in appetite, the majority of the study subjects in (week 1 and 16) had change in appetite more than before, while the majority of them in week 48 and week 72 had a little change than before. These findings are consistent with Moore& Dusheiko (2005) who stated that, ribavirin may have a role in side effects such as insomnia and decreased appetite. One well known side effect of ribavirin affecting HRQOL is anemia. Many people on pegylated interferon plus ribavirin experience

significant fatigue because they are anemic from the ribavirin.

The mean of the total depression scores in week 1 is 19.96 ± 3.82 , the total scores 17-20 patient on behave of depression, the mean in week16 is $22.38\pm$ 3.96, total scores 21-30 is mild depression, the mean in the week 32 and week 48 respectively are 17.54 ± 4.5 and 16.14 ± 1.85 , total scores 11-16 mood swings, and the mean in week 72 is 4.52 ± 2.39 , total score of 0-10 normal range(table 8). These study findings are consistent with Crone et al (2004) who interferon-induced stated that depression is considered a substance- induced mood disorder. Its symptoms are the same as those of major depression and include mood disturbance, fatigue, insomnia, sexual dysfunction and anorexia. cognitive impairment. Suicidal ideation may be present but tends to be relatively infrequent. The accompanying mood disturbance may be described as feeling sad or "blue" but it may also consist of marked irritability.

Table(9) revealed that, there is a significant correlation between the total scores of depression and total knowledge scores in week 1 with week 1(.375, which is significant at the 0.01 level), and week 32 with week 1(-.333, which is significant at the 0.05 level). One study done by Onyike *et al*, (2004), found that, while fatigue and depression both negatively affect the HRQOL of people on combination therapy, the effect of depression far outweighed the effect of fatigue or any other side effect on the HRQOL in the experience of most patients.

Table(10) showed that, there is a significant correlation between the total scores of short form health survey and total depression scores in week 1 with week 1(-.401, which is significant at the 0.01 level), week 1 with week 32(.332, which is significant at the 0.05 level), week 16 with week 16. 32, 48, 72(-.432, -.463, -.375 and -.537, which is significant at the 0.01 level), also, there is a significant difference between week 32 with week 1, 32, 72(.472, -.520, -.520, respectively which is significant at the 0.01 level) and a significant difference between week 32 with week16(-.330, which is significant at the 0.05 level), additionally, there is a significant difference between week 48 with week 48(-.431, which is significant at the 0.01 level) and a significant difference between week 48 with week 72(-.316), which is significant at the 0.05 level), finally, there is a significant difference between week 72 with week 72(-.470, which is significant at the 0.01 level). Psycho-education including psychotherapy, support groups, and educational groups, and provide education about depression and other neuropsychiatric symptoms, treatment options, and emotional support during a distressful period. Finally, given that clients with hepatitis C virus will be treated with IFN- alpha therapy, psychiatric nurses and other healthcare providers must monitor clients who are receiving IFN-alpha-induced therapy for the development of depression, particularly between the second and fifth months of treatment (Otong, 2003).

5. Conclusion

Based on the results of the present study, it can be concluded that, patient education and effective treatment are the cornerstones for enabling the patient to adhere to a therapeutic regimen. Monitoring the patient and dose adjustment during the treatment period is necessary. Lack of awareness about the route of application results in early termination of the treatment, as a result, a study of education of the patient in the proper method of the self-injection of interferon and the method of familiarizing him or her with the side effects and coping with it is essential and will lead to an improved quality of life.

Recommendations

Based on the study findings, it was recommended:

- Control of the hepatitis C epidemic in Egypt by a comprehensive viral hepatitis control program, raising community awareness, and ensuring safe blood supply.
- Before starting antiviral therapy, patients must be instructed about the schedule and the side effects to be expected during treatment. Patients should be instructed about the preventive and therapeutic measures to ameliorate these side effects for e.g. using antipyretics, analgesics, or antidepressants.
- Hepatology nurse specialists need to improve their skills in relation to counseling, support, education, and referrals that provide the greatest opportunity for staying on treatment and receiving care.
- Teach patients self administering interferon injections for patients living a far distance from the clinic and are usually more comfortable injecting at home to avoid frequent trips to the interferon clinics and patients may often reduce the impact of the flulike symptoms by self-injecting PEG IFN at home before bed time.
- Replication of the study on a large sample and in different hospital settings is recommended for generalization of results.

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