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Effect of Nursing Intervention Program on Interferone side Effects among Hepatitis C Patients

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Abstract: Interferone treatment for chronic hepatitis C produces a number of well-described side effects that are dominated by fatigue, influenza-like symptoms, hematologic abnormalities, and neuropsychiatric symptoms. ***The study aims*** to assess effect of nursing intervention program on interferone side effects among hepatitis C patients. ***Material and method:*** A convenience sample of 100 hepatitis C patients of both sexes in liver institute – Menoufia University was selected for data collection. Tools for data collection included Tool 1: Structured interview questionnaire. It includes 3 parts to assess medical data, lab investigation, and side effect. Tool 2 : patient knowledge questionnaire . Tool 3: Health Related Quality of Life (HRQOL). ***Results:*** All studied sample had several complains related to Interferon before giving the nursing management. Also there were statistical significance differences in all laboratory findings. There were statistical significant improvement of the knowledge and quality of life after 3 and 12 months from beginning of the study. Also, there was significant reduction in side effect of interferone therapy after 12 months from beginning of the study. ***Conclusion:*** nursing intervention and knowledge about chronic hepatitis C, its treatment and management of Interferon related side effects seemed to have positive effects on improving patient's knowledge about diseases and managing side effects of treatment and self-care modalities that reflected by improvement in laboratory findings, patients complain quality of life. ***Recommendation:*** Promotion & enhancement of the self-care modalities to the patient; a strict written instruction with pictures about disease process, prohibited and allowed foods, rest and physical activities and follow up should be continued after termination of the treatment through a rehabilitation program.

Keywords: Nursing intervention, selected side effects, Interferon and Ribavirin, Hepatitis C

BACKGROUND

Viral hepatitis is a systematic viral infection in which necrosis and inflammation of liver cells produce a characteristic cluster of clinical, biochemical, and cellular changes. The disease is important because it is easy to transmit; it has high morbidity and causes prolonged loss of time from employment. HCV is the underlying cause of about one-third of cases of hepatocellular carcinoma, and it is the most common reason for liver transplantation (Zic, 2005)

Hepatitis C virus (HCV) primarily attack the liver and the chronic hepatitis C infection is now recognized as an important and global health care problem that afflict about 170 million individual worldwide, the high incidence of hepatitis C virus (HCV) makes it one of the greatest health threats facing the world today (Rhoads 2003). Epidemiological data suggested that those with the highest prevalence of HCV are 20-39 years of age. Among those individuals and in the twenty- five years following initial infection, twenty to twenty five percent develop cirrhosis and three to five percent develop fatal complications such as hepatocellular carcinoma which results in an estimated death rate of 8000 to 10000 annually from hepatitis associated chronic liver diseases. (Rosen and Martin 2000).

Liver hepatitis C continues to be a public health problem in Egypt. Its incidence may be increasing and its prevalence is the highest reported worldwide. The overall prevalence of anti HCV was 18.9 % (El Hennawy 2008). While (Allen 2006) reported that an estimated 15 to 20 percent of the population has been exposed to hepatitis C compared to less than 5 percent in neighboring Sudan and 2 percent in the United States. In some areas of Egypt the rates are even higher. The infection rate among Egyptians 10 to 50 years old was 19.4 percent in southern Egypt, 26.5 percent in central Egypt and 28.4 percent in northern Egypt. Also in Egypt, patient admission in the National Liver Institute Hospital has been increasing at a very high rate over the past years. In 2002, more than 90,000 patients received treatment in outpatient's clinics and inpatients services that double the number for 1999. (Mohsen 2011)

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 the treatment for HCV involves a combination of two drugs: Pegylated Interferon (a subcutaneous injection that is given once weekly) and Ribavirin tablets that are taken orally each day. In some patients (depending on genotype), this treatment has been shown to induce a sustained viral response (SVR), defined as undetectable hepatitis C PCR for six months after the end of treatment. Treatment of HCV resulting in an SVR prevents progression of liver fibrosis and may improve life expectancy. Studies have also found that patients who do not experience an SVR may benefit from the temporary decrease in liver inflammation and fibrosis while taking treatment (Fried 2002) .

Adverse effects may differ slightly between types of IFN but primarly include flu-like manifestation: Headache, fatigue, fever, chills, , myalgia, and, dizziness, insomnia , insomnia; respiratory effects such as cough; gastrointestinal effects such as nausea, anorexia , and abdominal pain; and hemolytic anemia, the most frequent side effect, may be severe enough to require discontinuation of treatment (Fried 2002) . INF therapy is associated with significant side effects that include constitutional, neuropsychiatric, hematologic and hepatic responses. Interferon alfa and Ribavirin can be categorized to five group which are constitutional symptoms (flu-like symptoms) such as fever, myalegia, headache, chills and fatigue that varies from mild to severe, occurs in up to half of all patients and may start two to three hours after the drug is given ,injection site reaction, hematological side effects including anemia, thrombocytopenia and neutropenia that make patients more vulnerable to infection, bleeding or bruising, neuropsychiatric side effects and thyroid disorders (Mohsen 2011).

Moreover (Mulhall and Younossi 2005) reported that among the most prominent neuropsychiatric side effects are symptoms of depression and cognitive impairment. These side effects can also increase the risk for patient non-compliance with antiviral therapy and negatively impact the patient quality of life. Anti-viral therapies are associated with a decline in quality of life, which returns to baseline when therapy is terminated. Therefore, the effect of therapy on quality of life is best assessed not during therapy but once therapy is completed. Sustained viral response rates correlate positively with improvements in quality of life (McHutchison et al 2001). Unfortunately, non-responders to combination interferon and ribavirin therapy are not received good nursing intervention and knowledge about the treatment and the adherence to it. This group does not see any significant improvements in quality of life at the end of therapy, regardless of the therapy received. (Raseneck et al 2003).

Nurses are in a key position to carry out health education since they are the health care providers who have continuous contact with patients and their families and have the best opportunities to assess potential problems or side effects, discuss medical regimen and give teaching about all aspects of care which includes maintaining physical activity, recognizing activity limitations, conserving energy, following dietary modifications and adhering to medication schedule with attending to side effects. Simple measures to prevent or treat these side effects are adequate hydration by drinking plenty of liquids (two to three quarts of fluids per 24 hours), light to moderate regular exercises, alternating schedule of injection days with lighter workloads, giving injection in different places, conserve energy by getting plenty of rest and maintain nutrition. (Black et al 2005). offering small frequent meals by offering four to six per day which can prevent gastric distension that increase anorexia and fatigue, being in high fowler position during meals, arranging medication schedule so that it doesn't interfere with meals and discouraging smoking and intake of caffeine beverage as tea and cola.(Ewart et al 2004)

Aim of the study:

The aim of this study was to assess effect of nursing intervention program on interferone side effects among hepatitis C patients

Research Hypothesis:

- HCV patients treated with interferon who receive an enhanced educational intervention will fewer complain of side effects of interferone than those who do not receive.
- Knowledge level score among study group will be increased than control group patients.
- Quality of life among patients who receive nursing intervention will be improved than patients who do not receive.

Subjects and methods:

Research design:

A quasi experimental research design was utilized to achieve the aim of this study.

Setting:

The study was conducted at out-patient clinic in National Liver Institute Menoufiya University.

Subjects:

A Convenient sample of 100 HCV patients received interferon therapy . Sample size calculation for this case control study rendered 100 subjects (50 subjects in each group) based on 4% prevalence rate of HCV patients according to EL-Zanaty, and Way. (2008) with at least 80% power at Two-sided 95% significance level and ratio of case / control 1: 1. $n = (\frac{r+1}{r}) \frac{\sigma^2 (Z_\beta + Z_{\alpha/2})^2}{(\text{difference})^2}$ They were assigned randomly and alternatively divided into two equal groups, 50 patients for each groups. Study group (I): received comprehensive nursing intervention , Control group (II): exposed to routine hospital care. Patients were selected according to the following criteria:

- Serum HCV RNA was positive, be 18 -50 years old
- Receive one dose of interferone
- Compensated HCV infection, Alanine aminotransferse (ALA) upper normal limits
- Mentally alert, cared for themselves
- Able to read and write, and had a telephone and willing to participate.

The following patients were excluded if:

- Decompensate liver cirrhosis
- Dementia documented by attending physician
- Cardiovascular disease, renal insufficiency, , poorly controlled diabetes mellitus
- Immunologically mediated diseases (inflammatory bowel disease such as Crohn's disease, ulcerative colitis), systemic lupus erythematosus, autoimmune hemolytic anemia
- Thrombocytopenic purpura, , hemoglobinopathy
- Terminal illness with life expectancy less than 6 months, or refused to participate.

Tools of data collection:

The first and second tools were developed by the researcher after reviewing the related literature. While tool three was developed by Younossi, , at al. (2001)

Tool 1: Structured interviewing questionnaire:

It was developed and used by the researcher after reviewing the related literature to assess patient's medical data. It include 2 parts

Part one*:* Sociodemographic data such as age, sex, marital status, education and occupation.

Part two*:* laboratory investigations (Alanine aminotransferse (ALA)and Asperate (ASA) aminotransferase, Albumine, bilirubine , PCR, White blood cell count (WBC), Red blood (RBC) cell counts, Hemoglobin level (HB), Platelets,) .

Tool II: Patient Knowledge Questionnaire:

It was developed by researcher to assess the patient knowledge about:

- Disease process (definition, causes, signs , symptoms and treatment)
- Drug used (name, action, dose, route of administration and frequency)
- Side effects of the drug taken
- Measures used to manage these side effects (drinking plenty of fluid, eating food, practicing exercise, and taking rest)

Tool III: Health Related Quality of Life (HRQOL):

Quality of Life, defined as the degree to which aspects of patient's physical, social, functional, and emotional well-being are impacted by health 8. Quality of Life was measured using Scoring Instructions for the 36-Item Short Form Survey (SF-36). The SF-36 is a tool composed of 36 questions which is used to measure generic health status. The 36 questions measure 6 domain scales; physical function, role limitations, general health perceptions, pain, social function, role limitations—emotional, and mental health. 6 Domain scale scores are linearly transformed onto a scale from 0 (worst health) to 100 (best health). Sub scores assessing mental and physical health summary (MCS and PCS respectively) scores are also generated. The SF-36 has demonstrated good reliability and validity in primary care and chronic disease populations including chronic hepatitis C infection. (Younossi, et al. 2001)

Field work:

- Patients were recruited through outpatient clinics of National Liver Institute Menoufia University. The institutional review board approved the protocol and then consent was obtained from the patient.
- Permission from responsible authorities to carry out the study was obtained
- Data collection extended from the first May, 2010 until August, 2011. Patients who agreed to participate in the study and fulfilling the inclusion criteria were included in the study.
- Structured interview was used in order to fill the study tools. This technique provides a high response rate and allows the researcher to offer a protection against ambiguous or confusing questions.
- The researcher asked each patient started with interviewing schedule questionnaire tool then knowledge questionnaire tool about HCV, INF & side effects and measure used to decrease side effect. It took about 30 minutes to be filled out by the investigator to ensure consistency of data collection by using tool I and II.
- Assessment of health related quality of life (HRQL). This session took about 10 minutes for each patient.
- Health education: After collection of pre study data. The data obtained were meant to aid in formulating nursing management that tailored to suit patient's side effects. Each patient was scheduled for a minimum of 3 teaching sessions in three consecutive visits to outpatient clinics. Each session lasted 30 minutes for each patient.

- Session I: Patients received verbal instructions supplemented by written materials as an illustrative guide for more clarifications. Each patient was given health instructions about disease process as: definition, causes signs and symptoms and treatment; drug used for treating HCV as: name, dose, route of administration and frequency (15m)
- Session II : Health instruction about interferone, side effect (15 m)
- Session III : measure used to decrease side effect (15 m)

- Every patient in both groups (study and control) was assessed 3 times (pre intervention, after 3 months of intervention and after 12 months of intervention) for a side effect of treatment , knowledge, HRQL using tool 1,2 and 3,. Each one took about 30- 45 minutes.

Validity and Reliability:

All tools were tested for face and content validity by doing jury with academic staff consisted of 5 experts of various departments. 3 experts in the field of Medical Surgical Nursing, Faculty of Nursing, Menofia University, and 2 experts in the field of hepatology medicine, Faculty of Menoufia University. Modifications were done to ascertain relevance and completeness. All tools were tested using a test retest method and a person correlation coefficient formula was used. The period between each test was two weeks. It was 0.97 for tool one, 0.89 for tool two.

Pilot study:

The purpose of the pilot study was to ascertain the clarity, the applicability and the time needed to fill in the questionnaire. This study was conducted with a sample of 10 patients in total from National liver Institute. It is important to know those who participate in the pilot study were excluded from the main study sample. The feedback was considered and applied to develop the final form of the questionnaire.

Administration and ethical consideration:

The protocol was approved by the ethical committee. Patients were approached and informed about the purpose of the study before being asked to participate and an oral consent to participate in the study was obtained from them. The assurance of anonymity will be addressed prior to the request for participation. Anonymity of participants will be provided in two ways: The participants are asked not to write their names on the questionnaire; all this information will be remained confidential. In addition, they will be reassured that their participation in the study is voluntary. Also they will be informed that they could withdraw from the study at any time if they decided not to participate.

Statistical analysis*:*

Data were revised, coded, tabulated and analysis in a personal computer using SPSS program -version 22. The

following statistical techniques were used frequencies and percentages .Data were presented using descriptive statistics in the form of frequencies and percentages for qualitative variables, and means and standard deviations for quantitative variables.

RESULT

Table (1) revealed that the most of studied sample is male, married, secondary educated, employee and their ages are ranged from 35-45 years old which represent the statistical values as (78%, 74%, 40%, 60% and 35.04 ± 6.16 average of age) for study group and (80%, 80%, 44%, 50% and 33.06±7.24 average of age) for control group. There is no significant statistical difference regarding demographic characteristics with p- value >0.05

Table (2) clarified that there were significance differences of Albumine, PCR, WBC and RBC level pre intervention and after 12 months. While there were highly significance differences of asparate aminotransferase (AST), bilirubine, hemoglobin (Hb) and platelets pre intervention and after 12 months

Table (3) showed that there was an improvement in the mean total score of knowledge about HCV definition, causes, manifestations, treatment , dose, rout, frequency and duration) in the study group higher than control group after 3 month and 12months of intervention (2.89 ± 1.48 at pre intervention to become 8.61 ± 1.27 and 8.81 ± 1.68 at post intervention respectively. A highly statistical significant difference was existed between the study and control group in relation to knowledge score with p-value equal (< 0.001).

Table (4) clarified that about (90%) of study and control group had fatigue and weakness while after 12 months become (50% & 80%) of the study and control group. As regarding to headache and insomnia it's found that (80%) of the study group and (84%) of the control group had headache and insomnia pre intervention while after 12 months become (40%) of the study group and (88%) of the control group. concerning to muscle and bodyache the majority of both groups complaint of headache and body ache pre intervention and at the end of treatment decreased to (60% & 80%) of the study and control group. In relation to loss of appetite, pre intervention all of both groups had loss of appetite, while about (50% &80%) of study and control group their appetite were lost . There was significant difference were found between study and control group

Table (5) Part I. Revealed that regarding frequency of practicing exercise (6%) of the study group practiced exercise weekly as compared to (6 %) of the control group pre intervention while after 3 month and 12 month (70 % &74%) of the study practiced exercise weekly as compared to (6% & 8 %) of the control group. Regarding to amount of fluid per day before intervention it observed that about (14% & 12%) of the study and control group drink about 2 liters per day while after 12 month of intervention the about (64% & 6%) study and control group drink 2 liters of fluid per day. As regards eating foods that decrease side effect about (46% &44%) of the study and control group eating food that decrease side effect while After 12 months (86% & 50%) of study and control group. In relation to taking rest everyday pre intervention and after 12 months the study group took rest everyday (36% & 84%) while (40% & 58%) of the control group took rest. There was significant differences were found between study and control groups in relation

Table (5) Part II. Showed that there was an improvement in the mean total score of knowledge about the measures used to manage side effect of interferone at 3 times intervals , pre intervention, after 3 month of treatment , and 12 month of treatment. (4.89 ± 1.48 at pre intervention to become 20.66 ± 3.48 and 17.81 ± 4.48 at post intervention respectively. A highly statistical significant difference was existed between the study and control group in relation to knowledge score with p-value equal (< 0.001).

Table (6). Demonstrated that the majority of study group had moderate QOL versus the majority of control group had low HQOL after 12 months of treatment (60 % & 42% respectively). There were significantly lower percent of patients with low QOL after 12 months of treatment of the study than control group, where P value = 0.03.

Table (1): Comparison between two studied groups regarding socio- demographic criteria

Socio –demographic criteria	**Study group**		**Control group**		**X2**	**p-value**
	No	%	No	%		
Age:						
25<35	10	20	12	24	2.01	>0.05
35<45	35	70	33	66		
45<55	5	10	5	10		
X±SD						
	31.5400± 6.4		**33.06± 7.24**			
Gender:						
Male -	39	78	40	80	1.17	>0.05
-Female	11	22	10	20		
Marital status:						
-Single	7	14	3	6	4.38	>0.05
- Married	37	74	40	80		
-Divorced	4	8	5	10		
-Widowed	2	4	2	4		
Education:						
-Read and write	2	4	5	10	2.04	>0.05
-Primary education	15	30	16	32		
-Secondary	20	40	22	44		
-University	13	26	7	14		

Occupation:						
-Employee	30	60	25	50	3.15	>0.05
-Unemployed	20	40	25	50		

Table (2): Comparison between both study and control groups regarding to lab investigations at 3 times intervals (pre intervention, after 3 month of treatment, and 12 month of treatment).

Lab investigations	**Pre intervention**		**After 3month**		**After 12 month**	
	Study group (n=50)	**Control group (n=50)**	**Study group (n=50)**	**Study group (n=50)**	**Control group (n=50)**	**Study group (n=50)**
	X±SD	**X±SD**	**X±SD**	**X±SD**	**X±SD**	**X±SD**
ALT:	53.2 ± 24.5	51.6 ± 21.6	42.5 ±22.4	43.4±15.9	40.5 ±20.4	41.4±18.9
P value	**0.623 NS**		**0.733 NS**		**0.533 NS**	
AST:	47.4 ± 19.4	47.1± 17.6	36.28 ± 6.43	41.7 ± 16.1	31.28 ± 6.43	41.7 ± 16.1
P value	**0.918 NS**		**0.05 S**		**0.001 HS**	
Albumin:	4.284 ± 0.427	4.297 ± 0.456	4.158 ± 0.522	3.947 ± 0.725	4.87 ± 0.522	3.947 ± 0.725
P value	**0.835 NS**		**0.019 NS**		**0.05 S**	
Bilirubin :	1.034 ± 0.390	1.028 ± 0.368	1.008 ± 0.311	1.002 ± 0.368	0.588 ± 0.311	0.832± 0.368
P value	**0.923 NS**		**0.05 S**		**0.001 HS**	
PCR	1415246 ±141525	571334± 57133	1502 ± 3486	1224 ±1449	502 ± 1435	1024 ±1345
P-value	**0.198 NS**		**0.462 NS**		**0.004 S**	
WBC:	6562 ± 1828	6700 ± 1863	3021 ± 593	3040 ± 699	3606 ± 693	3840 ± 699
P value	**0.597 NS**		**0.763 NS**		**0.02 S**	
RBC	4164400 ± 953330	4319000 ± 745802	382220 ± 664468	382530±702274	398566±664468	352530±702274
P value	**0.203 NS**		**0.974 NS**		**0.02 S**	
HB:	14.23 ± 1.64	13.93 ± 1.55	11.45 ± 1.34	8.33 ± 1.45	12.39 ± 1.34	9.21 ± 1.68
P value	**0.189 NS**		**0.03 S**		**0.001HS**	
Platelets :	255806 ± 297737	255806 ± 297737	13163 ± 13828	131780 ± 25358	14274 ± 15828	132980 ± 25358
P value	**1.000 NS**		**0.123 NS**		**0.001 HS**	

test P value: NS= non-significant S= significan

Table (3): Distribution of both study and control groups as regards to total knowledge score about (HCV definition, causes, manifestations, treatment , dose, rout, frequency and duration) at 3 times intervals (pre intervention, after 3 month of treatment , and 12 month of treatment).

Knowledge about disease	**Pre intervention**				**After 3month**				**After 12 month**			
	Study group (n=50)		**Control group (n=50)**		**Study group (n=50)**		**Control group (n=50)**		**Study group (n=50)**		**Control group (n=50)**	
	No	**%**	**No**	**%**	**No**	**%**	**No**	**%**	**No**	**%**	**No**	**%**
Total score of knowledge about disease : Mean±SD	2.89±1.48		2.54±1.13		8.61±1.27		4.66±0.92		8.81±1.68		4.46±0.97	
Mann-Whitney test (U)	1.03				4.37 *				3.73			
P value	0.31 NS				<0.001 HS				<0.001 HS			
Total score categories:												
Poor (< 50%)	33	66	30	60	6	12	30	60	4	8	30	60
Fair (50-< 80%)	9	18	8	16	17	34	8	16	6	12	8	16
Good (≥ 80 %)	8	16	12	24	37	74	12	24	40	80	12	24
χ^2	1.74				18.21				14.11			
P value	0.42 NS				<0.001 HS				<0.001 HS			

P value: NS= non-significant HS= highly significant

Table (4): Distribution of both study and control groups as regards to side effect of inerferone at 3 times intervals (pre intervention, after 3 month of treatment, and 12 month of treatment).

Side effect of interferone	**Pre intervention**				**After 3month**				**After 12 month**			
	Study group (n=50)		**Control group (n=50)**		**Study group (n=50)**		**Control group (n=50)**		**Study group (n=50)**		**Control group (n=50)**	
	No	**%**	**No**	**%**	**No**	**%**	**No**	**%**	**No**	**%**	**No**	**%**
Fatigue and weakness:												
Present	45	90 %	45	90 %	30	60%	45	90	25	50	40	80
Not present	5	10 %	5	10 %	20	40%	5	10	25	50	10	20
Fisher's exact test	1.04				4.04				10.52			
P value	0.6 NS				0.04 S				0.001 HS			
Headache and insomnia :												
Present	40	80 %	42	84%	35	70%	47	94	20	40	44	88
Not present	10	20 %	8	16 %	15	30%	3	6	30	60	6	12

Fisher's exact test **P value**	1.00 0.8 NS				6.67 0.009 S				10.52 0.001 HS			
Muscle and body ache: Present Not present **Fisher's exact test** **P value**	45 5	90 % 10 %	45 5	90 % 10 %	40 10	50% 50%	45 5	90 10	30 20	60 40	40 10	80 20
	1.04 0.6 NS				1.02 0.31 NS				6.67 0.005 S			
Loss of appetite: Present Not present **Fisher's exact test** **P value**	50 0	100% 0%	50 0	100% 0%	35 15	70% 30%	45 5	90% 10%	25 25	50 50	40 10	80 20
	---- ----				9.3 0.005 HS				10.02 0.001 HS			

P value: NS= non-significant S= significant HS= High significant

Part (I) Table (5): Distribution of both study and control groups as regards to patients' measures used to manage side effect of interferone at 3 times intervals (pre intervention, after 3 month of treatment , and 12 month of treatment).

Knowledge about measures used to manage side effect	**Pre intervention**				**After 3month**				**After 12 month**			
	Study group (n=50)		**Control group (n=50)**		**Study group (n=50)**		**Control group (n=50)**		**Study group (n=50)**		**Control group (n=50)**	
	No	**%**	**No**	**%**	**No**	**%**	**No**	**%**	**No**	**%**	**No**	**%**
Frequency of practicing exercise: Daily Weekly Monthly Didn't practice χ^2 **P value**	5 3 4 38	10 6 8 76	3 3 2 42	6 6 4 84	5 35 5 5	10.0 70.0 10.0 10.0	3 3 14 30	6.0 6.0 28.0 60.0	10 37 3 0	20.0 74.0 6.0 0.0	6 4 13 27	12.0 8.0 26.0 54.0
	1.02 0.60 NS				19.71 <0.001 HS				24.13 <0.001 HS			
Amount of fluid per day Less than one litter One liter 2 liters 3 liters χ^2 **P value**	27 12 7 4	54.0 24.0 14.0 8.0	25 14 6 5	50.0 28.0 12.0 10.0	10 12 25 3	20.0 24.0 50.0 6.0	30 9 9 2	60.0 18.0 18.0 4.0	5 10 32 3	10.0 20.0 64.0 6.0	25 20 3 2	50.0 40.0 6.0 4.0
	2.69 0.44 NS				18.51 <0.001 HS				20.01 <0.001 HS			
Eating foods that decrease side effect Yes No **Fisher's exact test** **P value**	23 27 0.07 * 0.79 NS	46.0 54.0	22 28	44.0 56.0	40 10 16.07 <0.001 HS	96.7 3.3	24 26	48.0 52.0	43 7 19.45 * 0.001 HS	86.0 14.0	25 25	50.0 50.0
Taking rest everyday Yes No **Fisher's exact test** **P value**	18 32 0.08 * 0.80 NS	36 64	20 30	40 60	38 12 19.07 <0.005 S	76 24	21 29	42 58	42 8 23.30 * 0.001 HS	84 16	29 21	58 42

P value: NS= non-significant S= significant HS= highly significant

Part (II) Table (5): Distribution of both study and control groups as regards to patients' knowledge score about the measures used to manage side effect of interferone at 3 times intervals (pre intervention, after 3 month of treatment , and 12 month of treatment).

Knowledge	**Pre intervention**				**After 3month**				**After 12 month**			
	Study group (n=50)		**Control group (n=50)**		**Study group (n=50)**		**Control group (n=50)**		**Study group (n=50)**		**Control group (n=50)**	
	No	**%**	**No**	**%**	**No**	**%**	**No**	**%**	**No**	**%**	**No**	**%**
Total score of knowledge : Mean±SD	4.89±1.48		4.54±1.13		20.66±3.48		5.46±1.49		17.81±4.48		4.96±1.47	
Student t test **P value**	1.03 0.31 NS				21.99 <0.001 HS				14.93 <0.001 HS			
Total score categories: Poor (< 50%) Fair (50-< 80%) Good (≥ 80 %) χ^2 **P value**	26 2 2	86.6 6.7 6.7	24 5 1	80.0 16.7 3.3	4 7 19	13.3 23.4 63.3	22 3 5	73.3 10.0 16.7	8 5 17	26.6 16.7 56.7	21 4 5	70.0 13.3 16.7
	1.70 0.43 NS				22.23 <0.001 HS				12.48 <0.001 HS			

Table (6): Comparison between both studied groups regarding total HQOL score at 3 times intervals (pre intervention, after 3 months of treatment, and 12 months of treatment).

Total QOL	Pre intervention				After 3month				After 12 month			
	Study group (n=50)		Control group (n=50)		Study group (n=50)		Control group (n=50)		Study group (n=50)		Control group (n=50)	
	No	%	No	%	No	%	No	%	No	%	No	%
Total score: Mean±SD	53.09 ± 4.56		54.10 ± 4.61		80.09 ± 4.56		50.10 ± 4.61		80.71±31.17		53.92±19.63	
t test	1.56				2.60				2.79			
P value	0.121 NS				0.01 S				0.012 S			
High (≥ 80 %)	10	20.0	5	10	9	18.0	8	16.0	15	30.0	11	22.0
Moderate (50-< 80%)	20	60.0	30	60	37	74.0	28	56.0	30	60.0	18	36.0
Low (< 50%)	20	60.0	15	30	4	8.0	14	28.0	5	10.0	21	42.0
χ^2	0.39				5.87				6.95			
P value	0.82 NS				0.05 S				0.03 S			

P value: NS= non-significant S= significant

DISCUSSION

Because of the world wide prevalence of hepatitis C virus and the associated cirrhosis and mortality, treatment is an important issue which may be carried out by combination therapy of Interferon and Ribavirin. Current treatment for chronic hepatitis C virus infection (HCV) can cure up to 95% of patients who undergo antiviral therapy. However, HCV medications have troublesome side effects, which can lead to dose reduction or discontinuation of therapy. (Porter, &Franciscus 2015) . Therefore, the current study is aimed to assess effect of nursing intervention program on interferone side effects among hepatitis C patients

The current study represented that the mean age of the sample was 31.5400± 6.4. This finding was in line with AL-gendi et al (2013) who revealed that the study subjects consist of 100 adult patients, their age range from 20-60 years old, as for gender; it consists of 70% male and 30% female . While the finding was lower than the results of Heneedy,(2009) who reported that the mean age of her study sample was 49.8±8.3 for study group and 49.3±8.7 years for control group. This may be explained by the large sample size of the current study which could be generalized. As regard to sex, the studied sample showed that, the majority of them were male. This was in line with Lankarani (2004 who reported that more than three fourth of studied sample were male.

Regarding Laboratory investigations: National Hepatitis C Program(2007) mentioned that Interferon can suppress bone marrow production of Red blood cells, White blood cells and platelets that leads to anemia, neutropenia and thrombocytopenia. This was in agreement with the findings of the current study in which the mean hemoglobin level, platelet count was decreased than normal level before giving the proposed nursing intervention. Also Lankarani (2004) mentioned that anemia and thrombocytopenia were the most significant hematological side effects of combination therapy in which there is usually a drop of approximately 2-3 g/dl of Hemoglobin level and 10-50% of platelet count.

Moreover findings of the present study showed significant improvement of Hemoglobin level, White blood count and Platelet count after application of the proposed nursing intervention. This was in agreement with Heneedy. (2009) who stated that nursing intervention for patients with liver diseases has a number of positive effects on physical responses including laboratory findings. The results of the current study revealed that the mean Asparate Aminotransferse and Alanine Aminotransferse were increased before applying the nursing intervention with a significant improvement after applying the nursing intervention. This was supported by Mohsen (2011) who showed that mean Asperate and Alanine Aminotransferse were decreased after patient education and this alteration was significant.

In relation to knowledge score level: the current study revealed the patients pre intervention denoted that majority of them lack any essential knowledge about (HCV definition, causes, manifestations, treatment , dose, rout, frequency and duration). This result was also in line with Zucker and Miller (2001) who found that a significant differences between control and study groups as regard to total knowledge scores after protocol of care. effects and how to manage it. Also AL-gendi. et al (2013) emphasized that those patients with liver diseases need education, counseling and support to enable them to adjust to their chronic illness and its treatment.. This may be attributed to the theoretical sessions that were provided to cover all aspects of hepatitis C virus (definition, causes, signs and symptoms, treatment, action, dose, route, frequency) which eventually increase patient's knowledge.

In the present study results of the current study showed that there was significant improvement of sample knowledge in approximately every aspects of knowledge given to them than pre intervention The educational sessions had given a significant increase in their knowledge about Interferon side effect. This finding was consistent with that obtained by Hezode (2012) who found that repetition teaching on patient medication have significantly increase their knowledge regarding dose, special precautions and possible side effects of drug.

As regarding the measures were taken to decrease side effect: The present study showed that there was significant improvement of sample knowledge regarding the measures (practicing exercise, drinking fluid, eating diet , taking rest) were taken to decrease interferone side effect. These results were consistent with Mohsen, (2011) who showed a statistical significant difference between before and after conduction the nursing management protocol that indicates an improvement of patients total mean score of knowledge after intervention.

In addition to the effect of diet, exercises, fluid intake and taking rest on side effect of interferone (fatigue, weakness, headache, insomnia, muscle and body ache, loss of appetite and depression): The study group who were received intervention about diet, exercises, fluid intake and taking rest had lower percentage of interferone side effect occurrence than control group. This finding of the study is supported by a study done by Seyam, M.S (2005)) who stated that diet, exercises, fluid intake and taking rest decreased side effect of interferone (fatigue, weakness, headache, insomnia, muscle and body ache, loss of appetite and depression) . Also Hezode C, (2012) stated that, light exercise can actually combat fatigue, give you more energy, and even boost your mood. Try exercising in brief spurts of 10 to 15 minutes. Also be sure to get plenty of rest during the day. Take short naps of 20 minutes when possible — just not too close to bedtime. Eat smaller, nutritious meals throughout the day and stay well hydrated to keep up your energy levels. It is recommended that drinking water right before and right after self-injection and stay well hydrated throughout the week and decrease the feeling of fatigue and body ache

More over Black et al.,(2005) reported that getting proper nutrition from a healthy diet is an important part of maintaining your overall health during this time. A majority of people undergoing HCV therapy report mild to moderate weight loss, for this reason, including fluid and food as part of your medical regimen will help maintain good health. Be sure to eat foods with high nutritional value. Fruits and nuts are good choices. Eat small frequent meals, sufficient quantities of vitamins and minerals. Exercise is also important, since it increases muscle mass, stimulates the appetite, helps keep the immune system strong, and combats fatigue, body ache, insomnia and depression.

In relation to quality of life: the current study findings confirmed there was improvement of quality of life among patients who were received health instruction about management of side effect. It is recommended that you drink water right before and right after self-injection and stay well hydrated throughout the week and decrease the feeling of fatigue and body ache It is recommended that you drink water right before and right after self-injection and stay well hydrated throughout the week and decrease the feeling of fatigue and body ache this result consistent with Younossi, et al (2014) who mentioned that side effects that interfere with quality of life, so it's important to manage side effects early, aggressively, and appropriately.

Also Younossi , et al (2015) stated current therapies are not yet good enough to eradicate the hepatitis C virus in all treated patients, factors regarding the impact of therapy on quality of life must be entertained and discussed with the patient, prior to embarking on a course of treatment. Anti-viral therapies are associated with a decline in quality of life, which returns to baseline when therapy is terminated. Hepatitis C treatment has also been associated with increased fatigue, and a decreased ability to function at work, at home and in school, for this reason these patient need more education about side effect management

CONCLUSIONS

The present study revealed that enrichment of patients with nursing intervention and knowledge about chronic hepatitis C, its treatment and management of Interferon related side effects seemed to have positive effects on improving patients knowledge about diseases and managing side effects of treatment and compliance of treatment that reflected by improvement in laboratory findings, patients complains and health related quality of life

RECOMMENDATIONS

a) Promotion and enhancement of the compliance of treatment ; a strict written instruction with pictures about disease process, allowed foods, rest and physical activities and follow up should be continued after termination of the treatment through a rehabilitation program.
b) Special attention should be given regarding teaching patients family members who have an active role in patient care to help them comply with the prescribed medical and nursing intervention.
c) Replication of the study using a large probability sample from different geographical areas to allow greater generalizability of the results.

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