

# Effect of educational program on the Awareness for Hepatitis C adolescent patients Adherent to Therapeutic Regimen

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**Abstract:** Hepatitis C represents a challenge to the health and wellbeing of the adolescent patients and to health care system. In recent years remarkable progress has been made in hepatitis management in Egypt and Peginterferon/Ribavirin combination therapy has become the slandered of care.

**Aim:** This study aimed to evaluate the educational program on the children awareness for hepatitis C adherent to therapeutic regimen namely interferon and ribavirin therapy.

**Methods:** A quasi-experimental design was utilized to conduct this study, the study was carried out at outpatient of National Hepatology and Tropical Medicine Research Institute at Cairo.

**Sample:** A purposive sample included 30 pediatric adolescents from the previously mentioned settings. Tools:1) Patients' interviewing sheet to assess their knowledge about therapeutic regimen (pre / post tests), 2) An observation checklist to evaluate patients' reported practices regarding therapeutic regimen (pre / post tests & follow up) Patients condition assessment (pre / post tests & follow up) and 5) Self-report weekly diary.

**Results:** Showed that, there were statistically significant differences between knowledge of the studied teachers throughout the intervention ( $X^2=27.4$ ;  $p=0.0001$ ) and there were statistically significant differences between practices of the studied teachers throughout the intervention ( $X^2=26.3$ ;  $p=0.0001$ ). Moreover, there was a positive correlation between total knowledge of the studied adolescents and their total practices throughout the intervention with statistically significant difference at  $p < 0.05$ .

**Conclusion:** Educational program were helpful in creating and improving the awareness for hepatitis C pediatric patients adherent to therapeutic regimen namely interferon and ribavirin therapy and reduction of treatment side effects,

**Recommendations:** Further studies should be carried out on a large number of hepatitis C patients for evidence of the results and generalization.

**Keywords:** Therapeutic regimen (interferon and ribavirin) - treatment adherence – educational program.

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## 1. INTRODUCTION

The number of hepatitis pediatric patients was increased last few years. The world health organization has declared HCV as a global health problem affecting 130–170 million people worldwide. In Egypt, it continues to be a public health problem and its prevalence is the highest reported worldwide. Moreover, many publications suggest that over 15% of people in Egypt are infected, which equal ten times greater than any other country in the world (*Ahmed & Abdel Al, 2008 and Mohsen et al., 2011*).

Remarkable progress has been made in the management of hepatitis C in recent years and Combination therapy (Peginterferon/Ribavirin) has become the standard of care. Treatment guidelines for chronic hepatitis C virus infection are based on a large number of published natural history studies and randomized controlled trials. There are fewer data available regarding the epidemiology, spontaneous course, and treatment of chronic hepatitis C in children and adolescents. Initially, most guidelines recommended adolescents to be managed and treated in a similar way as adults. Recently, several published open - label treatment trials have demonstrated significant efficacy and safety of HCV infection therapy in children and adolescents using either interferon- $\alpha$  2b or peginterferon- $\alpha$  2b in combination with ribavirin, which resulted in official approval of this treatment regimen by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA). As in adults, sustained viral response (SVR) depends on genotype. Patients infected with genotype 2 and 3 respond significantly better than those with genotype 1 or 4 who only have response rates of 50%. Therefore, half of the treated patients remain chronic virus carriers with a risk of progressive liver disease, so there are compelling reasons to improve the present treatment options (*Chary et al., 2010 and Nicol, 2010*).

Interferon is a substance naturally produced by the body to defend itself from infections and regulating cell function including the hepatitis C virus, and tumors. The Interferons used in treatment are synthetically manufactured and taken in much higher doses than would occur naturally in the body. Interferon was the first proven treatment for hepatitis C and effective for only a small number of people. It is given as an injection taken once a week for 24 – 48 weeks. Ribavirin which called nucleoside analogues, works by stopping the virus from spreading inside the body and comes as tablets taken three times a day. Younger patients who have mild liver disease and fewer virus particles in the liver usually respond better to interferon and ribavirin treatment (*Nadeem et al., 2007 and Noghabi et al., 2010*). Peglated Interferon which is the addition of a large polyethylene glycol (PEG) molecule to interferon produces a molecule that lasts a lot longer in the body, meaning that only one injection per week is required. This change has resulted in considerably fewer peaks and troughs in drug levels in the blood, greater tolerability and improved effectiveness in fighting the hepatitis C virus (*Thomas and Zoulim, 2012*).

In several large trials of hepatitis C treatment, a wide array of side effects have been encountered which are usually minor but are problematic for a significant proportion of patients. Major adverse events can occur, but life-threatening adverse events have been rare in large surveys. Tolerance in adult's patients and adolescents is usually similar. Early flu-like side effects are predictable and are encountered in the majority of patients. These tend to occur within 6-8 hours after starting treatment and are worst with the first injections. These side effects include fever, malaise, tachycardia, chills, headache, arthralgias, myalgias and tachyphylaxis which generally develop after the first few injections. Later side effects that develop after some days include; fatigue, malaise, apathy and cognitive changes. Moreover, Between 10 and 15 percent of patients find the chronic side effects intolerable and discontinue treatment. Higher doses tend to give higher rates of adverse events. Most symptoms can be managed with medical intervention and dose reduction (*Khalid et al., 2009, Stefan et al., 2011 and Velmishi et al., 2012*).

Adolescent patient education is necessary to develop the attitudes that influence positive health behaviors, understanding the rationale of taking medication correlates with the degree of compliance, severity of disease and the complexity of treatment regimens. Through education, patients can be aware of their disease process and potential treatment options. But, educating patients is not as easy as one might think. Patients come from different ethnic and socioeconomic backgrounds; and they have different treatment priorities. It's important to have an open discussion with patients and to get to know their expectations and needs. The main purpose of treating and caring for patients with chronic viral hepatitis is to promote life satisfaction and feeling of well-being (*Walsh, 2008, Noghabi et al., 2010 and Potter & Perry, 2011*).

#### **Aim of the study:**

This study aimed to evaluate the effect of educational program on the children awareness for hepatitis C adherent to therapeutic regimen namely interferon and ribavirin therapy.. This aim was achieved through the following:

- Assessing knowledge and reported practices of hepatitis C Adolescent patients regarding to therapeutic regimen (Interferon and Ribavirin).
- Developing and implementing educational program for hepatitis C adolescent patient's adherent to Interferon and Ribavirin therapy and evaluating its effect on their knowledge and reported practices.

**Hypothesis:**

It was hypothesized that there is a positive effect on the adolescent patient's awareness for hepatitis C adherent to Interferon and Ribavirin therapy.

## 2. SUBJECTS AND METHODS

**Research design:**

A quasi-experimental design was utilized to conduct this study.

**Setting:**

The study was carried out at outpatient *National Hepatology and Tropical Medicine Research Institute* at Cairo.

**Subjects:**

A purposive sample included

\* This study aimed to evaluate the educational program on the Adolescent patients awareness (knowledge and reported practices) for hepatitis C adherent to therapeutic regimen namely Interferon and Ribavirin therapy. (n = 30) with 15 – 18 years age were taken from *National Hepatology and Tropical Medicine Research Institute* at Cairo.

**Inclusion criteria:**

1. Adolescent patients with the first time treatment or have been received at least one time treatment
2. Adolescent patients adhere to the first three months of treatment
3. Adolescent patients with chronic hepatitis C and willing to participate in the study.

**Exclusion criteria:**

1. Unconscious Adolescent patients
2. Adolescent patients aged less 15 years old
3. Adolescent patients with speech disorders
4. Adolescent patients with chronic illness (kidney, heart, hypertension, autoimmune, liver cirrhosis, cancer, diabetes and anemia, .etc).

**Tools of data collection:**

**1 - Pediatric Patients' interviewing sheet (pre / post tests& follow up)**, which was developed in a simple clear Arabic language by the researchers based on literature review and experts' opinions in the light of relevant references to determine patients' knowledge regarding Interferon and Ribavirin therapy. It included the following parts:

- **The first part:** related to characteristics of the study subjects namely, age, gender, educational level and duration of diagnosis.
- **The second part:** related to patients' knowledge about chronic hepatitis C including: definition, causes, predisposing factors, types, manifestations, complications, management, prevention sources of their knowledge, treatment(name, dose and route of administration), side effects and its management, safety measures, investigations before ,after treatment and follow up physical preparations and treatment instructions.
- Answers of the studied Patients' were scored as (1) for correct answer and (zero) for incorrect answer. The total score of questionnaire will be 100 % and three score level accordingly, as more than 75% is consider good knowledge, from 60% to 75% will be consider average level of knowledge and less than 60% will be consider poor knowledge .

**2 - An observation checklist (pre / post tests)**, adapted from *Timby and Smith (2008), Walsh (2008) and Nicol (2010)*. It was developed and filled by the researchers to evaluate Adolescent patients reported practices regarding the following: infection control measures, self-injection technique, temperature and heart rate measurement, personal hygiene and exercises measures.

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The total score of questionnaire will be 100 % and three score level accordingly, as more than 75% is consider good practices, from 60% to 75% will be consider average level of practices and less than 60% will be consider poor practices.

**4- Adolescents patient's condition assessment sheet (pre / post tests & follow up)**, it was completed by interviewing of the studied patients to determine presence of the side effects.

**5 - Self - report weekly diary**, which designed by the researchers and completed at the same time of treatment sessions to identify Adolescent patients' complaints and the solutions that have been already done. This report was helpful in the assessment of patient s' condition and prevent further complications.

### Face and content validity:

It was ascertained by a group of experts from pediatric (2), Tropical Medicine and Gastroenterology (1). Their opinions were elicited regarding to the tools format layout, consistency and scoring system. Contents of the tools were tested regarding to the knowledge accuracy, relevance and competence.

### Ethical considerations and human rights:

In the planning stage approval was obtained from the directors of the above mentioned settings. All Adolescents patients were informed about the study and their rights according to medical research ethics that they were free to decide whether or not they would participate in the study. Then a written informed consent was obtained from each patient who agreed to participate in study.

The tools were ascertained by a group of five experts in the field of pediatric nursing to test the content validity. Their opinions elicited regarding the format, layout, consistency, accuracy, and relevancy of the tools. The reliability of the tools was assessed by measuring their internal consisted. Knowledge tool (Cronbach's alpha = 0.86) and practices tool (Cronbach's alpha = 0.82).

### Pilot study:

A pilot trial was carried out on 10% of the total study sample to test the clarity, feasibility and practicability of the tools, in addition to subjects and settings. Pilot subjects were later included in the study as there were no subsequent modifications in the study tools.

### Procedures:

- The study was implemented during period of 6 months and the educational program were designed based on analysis of the actual educational Adolescents patients' needs assessment in pre test by using the pre constructed tools.
- The content was written in simple Arabic language and consistent with the related literature. Moreover, met Adolescent patients' needs and their level of understanding.
- The educational program was presented in theoretical and practical sessions. Sample was divided into small groups including 4 – 5 patients and repeated sessions included all Patients, each group obtained 4 sessions. In addition, each patient was guided by written instructions, and then orientation about objectives, outline and expected outcomes was done.
- The theoretical part was conducted through lectures and group discussions, using data show as a media. It was taken in 3 sessions (each session for 45 minutes) and covers the following items: interferon- ribavirin therapy indications, side effects management, physical, psychological preparations, correct diet and infection control measures.
- The practical part was conducted through demonstration, teach - Back and video. It was taken in 3 sessions (each session for one hour) and covers the following items (self- injection technique, temperature and heart rate measurement, exercises technique and infection control measures).
- Adolescents patient's condition assessment sheet was assessed through the weekly dairy of self report at the same time the patients present for treatment sessions. Results of the weekly diary were tabulated as follows:
  - \* On the first time of treatment.
  - \* After 4 weeks of treatment
  - \* After 8 weeks of treatment

- The researchers contact the Adolescents patients one day weekly for any explanation. Adolescents patients were also informed to be in contact with the researchers by telephone for any guidance.
- Adolescents patients were assessed either individually or in groups that entail 4-5, according to their physical and mental readiness.
- Evaluating the effect of educational program on the studied sample knowledge and reported practices, presence of side – effects were implemented by using post – test (one month after pre – test) and follow- up test (two months later) by using the same tools.

#### 4. Statistical Analysis:

Data collected from the studied samples were revised, coded and entered and statistical analysis was fulfilled using the Statistical Package for Social Sciences (SPSS), version 20. Data were presented in accordance with their distribution: as ranges or mean and SDs. Categorical data were tested with the Chi-square test ( $X^2$ ) for qualitative variables and independent sample t-test for quantitative variables. Statistical significance was considered at p-value <0.05.

### 3. RESULTS

Table (1): Presents characteristics of the studied adolescents patients, this table clarified that mean age of adolescents patients was  $17.5 \pm 1.5$ . More than half of patients of adolescents were male. Also, the current table revealed that less than half of them adolescents had low educational level, as regards the duration of patient's diagnosis this table clears that, more than half of patients were diagnosed with more than one years.

Table (2): clarifies that there were statistically significant differences between knowledge of the studied teachers throughout the intervention ( $X^2=27.4$ ;  $p=0.0001$ ).

Table (3): Shows that there were statistically significant differences between practices of the studied teachers throughout the intervention ( $X^2=26.3$ ;  $p=0.0001$ ).

Table (4): Reveals patients' condition assessment in pre/post tests. Results revealed reduction on mean percent of side-effects among adolescents after one month of treatment, followed by two months later. Furthermore, significant differences were found between adolescents patients as regards side - effects throughout the intervention ( $p<0.05$ ).

Table (5): Results illustrates the positive correlation between total knowledge of the studied adolescents and their total practices throughout the intervention with statistically significant difference at  $p< 0.05$

**Table 1: Distribution of the adolescents patients according to their characteristics (n=30)**

Items	Adolescents (n=30)%
Age / years	
Mean $\pm$ SD	$17.5 \pm 1.5$
Gender	
Male	80.0
Female	20.0
Level of education	
High	-
Moderate	62.0
Low	38.0
Income	
Enough	41.0
Not enough	59.0
Diagnosis duration	
< 1 year	45.0
$\geq 1$ year	55.0

\*High education: University - Moderate education: Secondary school and technical institutions - Low education: Illiterate, read and write, primary

Table 2: Distribution of the adolescents patients according to their knowledge throughout the intervention (n= 30)

Levels	Knowledge						X2	P Value
	Pre Intervention		Post Intervention		Follow up			
	No	%	No	%	No	%		
Good	3	10.0	13	43.3	10	33.3	27.4	0.0001
Average	8	26.7	14	46.7	16	53.4		
Poor	19	63.3	3	10.0	4	13.3		

Table 3: Distribution of the adolescents patients according to their practices throughout the intervention (n= 30)

Levels	Practices						X2	P Value
	Pre Intervention		Post Intervention		Follow up			
	No	%	No	%	No	%		
Good	2	6.7	9	30.0	9	30.0	26.3	0.0001
Average	6	20.0	15	50.0	16	53.4		
Poor	22	73.3	6	20.0	5	16.6		

Table 4: Distribution of the adolescents patients according to their condition assessment (side effects reduction) throughout the intervention (n= 30)

Side effects	Pre Intervention				Post Intervention				Follow up				X2	P Value
	Present		Not present		Present		Not present		Present		Not present			
	No	%	No	%	No	%	No	%	No	%	No	%		
Fever	4	13.3	26	86.7	23	76.7	7	23.3	13	43.3	17	56.7	24.4	0.0001
Anorexia	5	16.7	25	83.3	18	60.0	12	40.0	9	30.0	21	70.0	12.9	0.002
Fatigue	12	40.0	18	60.0	25	83.3	5	16.7	16	53.3	14	46.7	12.2	0.002
Headache	9	30.0	21	70.0	22	73.3	8	26.7	20	66.7	10	33.3	13.3	0.001
Insomnia	10	33.3	20	66.7	21	70.0	9	30.0	12	40.0	18	60.0	9.2	0.01
Worried	15	50.0	15	50.0	26	86.7	4	13.3	18	60.0	12	40.0	9.5	0.01

Table (5): Correlation between total knowledge of the studied adolescent patients' and their total practices throughout the intervention (n= 3)

Items	Knowledge					
	Pre Intervention		Post Intervention		Follow up	
	r	P	r	P	r	P
Practices	0.72	0.04	0.90	0.001	0.87	0.002

#### 4. DISCUSSION

Chronic hepatitis C in teens is usually silent, so it is known as silent killer (Khalid et al., 2009). Imperfect adherent to combination therapy is common in routine patients, so adherence is markedly over stimulated by physicians and is associated with some patients' baseline characteristics. Knowledge of these factors might help in identifying patients who are most in need of intervention, planning and accurate follow - up (Marcellin et al., 2011). Patient education can take place in any healthcare setting. But finding the best way to provide it and evaluating the results of teaching can pose a challenge. How well patients comprehend and recall the information they're taught helps to predict their adherence to management. The current study aimed to evaluate the effect of educational program on the awareness for hepatitis C adolescent patients adherent to therapeutic regimen. The present study clarified that, mean age of studied sample was 17.5±1.5. These findings were highly supported with Ahmed and Abdel Al (2008) and Mohsen et al. (2011) who reported that, the age of the studied sample was from 16-18 years old.

Concerning hepatitis C patients' knowledge and practices, the current study revealed that more than half of the studied sample had poor knowledge and practices in pre- test. Sandokji et al. (2003) and Sarasin-Filipowicz (2010) stated that providing information to patients about treatment regimens will increase their tolerance and compliance. In similar study of Mohsen et al. (2011), who stated that enrichment of patient with knowledge about chronic hepatitis C, its treatment and management related interferon side effects seemed to have positive effect on patient's condition, also, the study of Noghbi

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*et al. (2010)* clarified that, continuous education and follow - up in chronic hepatitis C patients under antiviral therapy could greatly increase their adherence to treatment and reduce side effects, ultimately resulting in a better goal. *Kogure et al. (2008)* cleared that patients education and effective treatment are cornerstones for enabling patients' to adhere to treatment. In addition, lack of awareness about route of application results in early termination of treatment.

In relation to patients' condition assessment, results revealed insignificant differences between adolescents regarding side effects in pre/post tests. The previous finding was supported by *Thomas and Zoulim (2012)* who reported that, side effects tolerance in adolescent is usually similar. *Sandokji et al. (2003)* and *Stefan et al. (2011)* were in accordance with the previous findings. In the same context, significant reduction on side-effects was observed in post-tests. *Noghbi et al. (2010)* recognized that, early flu-like side effects are predictable and encountered in majority of patients. It tends to occur within 6-8 hours after starting treatment and is worst with first injections. These side-effects include fever, malaise, tachycardia, chills, headache, arthraigias and myaigias. *Chary et al. (2010)* recommended that, using simple measures against side effects like adequate hydration, light to moderate physical activities, treatment schedule, sedatives and antipyretics. According to *Nadeem et al. (2007)* and *Khalid et al. (2009)*, treatment administration at night may reduce the frequency of side- effects. Moreover, array of side effects indicates the importance of selecting patients for therapy and optimizing response, careful assessment is required before treatment and monitoring is important during treatment. *Velmishi et al. (2012)* mentioned that, between 10 and 15 percent of patients find the chronic side effect intolerable and discontinue treatment.

Results revealed more significant improvement in post and follow up tests among studied patients having educational program. The previous findings could be attributed to the fact that, the program was given in this study using lectures, demonstration, video and teach back technique, According to *Xu (2012)*, who mentioned that Lecture has many advantages including the ability to provide information to a large number, the ability to cover a large amount of material quickly and provide cost effectiveness. The lecture is a way to introduce new material, continue discussion of a topic, and sum up course content, as well as present large blocks of complex and confusing information. According to *Friedman et al. (2011)*, Video education, is very similar to computer-based training. But, it is more difficult to evaluate learning. A written post-test could be used after the video is reviewed. But, it is important with both of these media to consider the patients' educational level, language, and hearing/seeing abilities. In addition, *Farrell et al. (2009)* stated that, Demonstration is an effective patient -teaching technique. Patients can be showed how to complete a task or how a process works in a one- on - one setting, and then they can do the task more effectively at home. It does ensure that patients fully understand the teaching and it allows them to get feedback and ask questions in a safe arena.

### 5. CONCLUSION

In the light of the current study it can be concluded that, educational program were helpful in creating and improving the awareness of hepatitis C adolescent patients adherent to therapeutic regimen (interferon and ribavirin therapy), moreover, significant improvement was observed on reducing treatment side effects among the studied adolescent patients. Also, it can be concluded that the result of the current findings support the research hypothesis.

### 6. RECOMMENDATIONS

- Awareness programs about interferon-ribavirin therapy should be held periodically for hepatitis C Adolescent patients.
- Self-care behavioral strategies should be developed to relieve side effects of treatment.
- Teaching family members to participate in Adolescent patients' care.
- Further studies should be carried out on a large number of hepatitis C Adolescent patients for evidence of results and generalization.

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