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# Effect of Applied Educational Program on Quality of Life of Hepatitis C Patient Undergoing Treatment With Pegylated Interferon And Ribavirin.

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***Abstract***
***Background:*** *The primary concern of all hepatitis C patients undergoing the antivaral therapy of Pegylated Interferon and Ribavirin is their health related quality of life (HRQoL), therefore an educational program is important for Those patients.*
***Aim of the study****; To investigate effects of applied educational program on quality of life of hepatitis C patient undergoing the treatment with Pegylated interferon plus Ribavirin.*
***Methods;*** *A quasi-experimental research design was utilized. The study was applied at outpatient clinic at Mansoura International Hospital. Participants (n=100) were randomly assigned to studied group (n=50) and control group (n=50). Participants of studied group have received an educational program intervention on the same day of first injection Pegylated Interferon. This program included three sessions. The first session include pre-assessment of quality of life. The second session lasted about one hour that included a presentation with the support of simple illustrating colored picture. While the last session was devoted to discussion and patients feedback. At the end of third session, hepatitis C overview booklet was given to the studied group. Two tests to evaluate the educational program effects were done, before applied intervention and one month after intervention.*
***Results****: There was statistically significant difference between studied and control groups of their HRQoL domains' total mean score after 1 -month post educational intervention as p=0.001* compared by pre-educational intervention p=0.915.*
***Conclusion****; Applied educational program reach significant difference Therefore, an educational program can add to enhance the quality of life of hepatitis C patient.*
***Keywords****: hepatitis C, quality of life, Pegylated interferon, Ribavirin*

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## I. Introduction

HepatitisC virus (HCV) infection is serious health issue. Chronic HCV infection is a major cause of cirrhosis, hepatic decompensation and hepatocellularcarcinoma. It is a ccounts for about 27% of cirrhotic cases and about 25% of hepatocellularcarcinoma (HCC) cases worldwide [1,2,3]. Inaddition to its huge financial impact on national level. In population of the Middle East, HCV prevalence has been shown to ranging from 1-12 % with the largest percentage occuring in Egypt, estimated nationally at 14.7%.[4,5,6,7,8].

HCV is a major public health problem with no vaccination yet available. [9] The different genetic types of HCV hampers the production of an effective anti-HCV vaccine but various treatments can eradicate the virus. [10,11] HCV treatment with Pegylated interferon and Ribavirin have a lot of side effects that negatively influence patients' health related quality of life, accordingly influencing their adherence to the treatment course to achieve sustained virological response (SVR) or cure. [12,13] The nurse is playing an important role in supporting hepatitis C patients and helping them to accept responsibility for their health and well being. The assistance of the nurse in patient's counseling about the relative risks, benefits of treatment and management of the side effects is playing an important role in, assisting them in understanding their health condition, preparing them for procedures and explaining to them how to provide self care for completing a treatment course to achieve a sustained virological response or cure. [14,15,16]

## II. Significant of Study

Egypt has a high reported prevalence rate of HCV. Therefore, the Egyptiant government established the National Committee for Control of Viral Hepatitis to provide a public treatment strategy **.** [18,19] Historical data from studies on the use of interferon-based regimens (interferon alone or interferon in combination with Ribavirin) showed that, patients suffered a significant drop in health-related quality of life (HRQLQ). [20,21] So, patient's quality of life during the antiviral therapy is an important clinical concern in individuals with HCV in order to avoid suboptimal therapy and/or unnecessary treatment discontinuations.

Development and implementation of an educational program will providing those patients with needed knowledge and support in order to help them to complete the treatment course for achieving a sustained virological response or cure and assisting them to manage their health problems which will improve their HRQLQ. [20,21] In addition to, the study of the patients' quality of life will provide an essential information about the effect of the disease and the treatment on, patient's general health and their adherence. Therefore, it seems imperative to assess patient's HRQLQ and to help them to manage the side effects to complete the treatment course. [14,22,23]

## III. Methodology

**3.1 Aim;**

To Investigate the effect of applied educational program on HRQLQ of HCV patients receiving antiviral therapy of Pegylated Interferon & Ribavirin.

**3.2 Research Hyposesis**

Hepatitis C Patient**s** who are given the educational program will exhibit better quality of life than patients who are received the routine hospital care.

**3.3Research design**

Quasi-experimental study was used in the research.

**3.4 Setting**

The study was applied at outpatient clinic at Mansoura International Hospital.

**3.5 Participants**

A convenient participants of 100 adult hepatitis C patient from both sexes, with a hemodynamic stability, willing to participate in the study and able to communicate, were involved in the study. The study participants were included two equal group; a studied group, consisting of 50 patients who received the educational program and a control group, consisting of 50 adult patients who received the routine hospital care only.

**3.6Tools**

Two tools were used for data collection in this study as the following;

**3.6.1 Tool I: Interview Hepatitis C patient's schedule questionnaire:** This tool was developed by the researcher to collect patient's socio-demographic and health relevant data. The demographic information included age, sex, marital status, education, and occupational status. The clinical data included family history, chronic disease history and laboratory investigations.

**3.6. 2 Tool II: Hepatitis C Quality of Life Questionnaire (HCQLQ)** : The Short Form-36 (SF-36) is a generic HRQOL instrument used in clinical trials that measures the physical, psychological, and social impact.[24,25] It consists of eight health concepts; physical functioning (10items), role limitations due to physical health (4items), role limitations due to emotional problems (3items), energy/fatigue (4items), emotional well-being (5items), social functioning (2items), pain (2items ), and general health (5items). HRQoL scores were presented as means and standard deviations for categorical variables.[26,27,28]

**3.7 Validity and reliability of the instruments:**

The developed tool was tested for content- related validity by seven experts of the nursing and medical staff who reviewed the tool.Then minor changes were done accordingly.

**3.8 Pilot study**

A Pilot study was applied on 10 hepatitis C subjects to examine the clarity and applicability of the tools. These patients were not included in the study sample. Tools were modified to be clear and understood.

**3.9 Ethical considerations**

The proposal was submitted for acceptance from research ethical committee, Faculty of Nursing, Mansoura University. Official written approval to apply the study at outpatient clinic at Mansoura-International hospital.

**3.10 Procedure**

1 Both study and control group were interviewed by the researcher at the day of first dose Pegylated Interferon injection and 1- month later.
2 Educational program was applied only for the studied group of the participants while control group received a routine hospital care.
3 The educational program facing three sessions. The first session included pre-assessment of patient's socio-demographic data, family history, laboratory tests and their health related quality of life. The second session lasted about one hour based on individual needs and tolerance. a presentation was given by the researcher with the support of simple illustrating colored picture. Last session was to discussion, suggestions and patients ' feedback.
**4** Two repeated assessment was taken (before the educational intervention and one month post- intervention).

**3.11 Statistical analysis;**

All data coded and analyzed by the Statistical Package for Social Sciences (SPSS). Qualitative variables were written as number and percentage. Quantitative variables were written as mean ± SD. To check the difference between two groups independent t-test, and Chi square ($\chi 2$), was used $P \leq .05$ was considered statistically significant.

## IV. Result

Table (1) showed that, Male patients made up 80% of the total study subjects, however, the percentage of males was higher in the studied group (82%) as compared to the control group (78%) but with no significant difference (p=0.617). The ages of patients varied from 28 years to 55 years in the studied group whereas the age range was between 21 years and 50 years in the control group. The average age of the studied patients was 39 years with a standard deviation of 9.44 years. While the average age of the patients in the control group was 35 with a standard deviation of 11 years. Furthermore, the highest percentage of patients in studied and control groups (86% &84%) respectively were married. Table(2) represented that, the laboratory tests of Albumin, Bilirubin, Prothrombin time, SGOT, and SGPT were in the normal range for most participants of studied and control group.

Table(3) showed that, nearly half of the participants had a family history of hepatitis c (48% of studied and 38% of control group), mostly of them were in the very close family members (first degree relations). The results also revealed that, most of the participants detected the disease accidentally, during a medical consultation of another health problem or through performing a bood screening for traveling abroad .

Table (4) showed that, regarding, HRQoL of the sample, mean scores of their responses were calculated for each domain. The data was collected before educational intervention as well as one month post-intervention. The results showed that, HRQoL after 1- month post educational intervention, was better in all domains except for role limitation due to physical or emotional problem. However, these domain remained same or worsened in the control participants, who was not attended educational sessions. The results also revealed that, the patient's ability to deal with their emotional issues related to the disease were in a much better way post the educational program. The results also illustrated that, total mean score of HRQoL of the participants after 1- month post educational intervention were differ significantly between the studied and control groups (p=0.001) as compared by pre-educational intervention ( p=0.915).

**Table (I) - Demographic data of the participants (n=100).**

| **Categories** | **Participants (n=100)** | | | | | | |
|---|---|---|---|---|---|---|---|
| | **Studied participants (n=50)** | | **Control participants (n=50)** | | **Total (n=100)** | | $\chi^2$ **P** |
| | **n** | **%** | **n** | **%** | **n** | **%** | |
| **•Sex:** | | | | | | | |
| Males | 41 | 82.0 | 39 | 78.0 | 80 | 80.0 | 0.250 |
| Females | 9 | 18.0 | 11 | 22.0 | 20 | 20.0 | 0.617 |
| **•Age (years)** | | | | | | | |
| **Range** | 28-55 | | 21-50 | | 21-55 | | |
| **Mean±SD** | 39.02±9.44 | | 35.06±11.06 | | 37.04±10.42 | | |
| **•Marital status:** | | | | | | | |
| Married | 43 | 86.0 | 42 | 84.0 | 85 | 85.0 | 0.790 |
| Single | 1 | 2.0 | 2 | 4.0 | 3 | 3.0 | 0.852 |
| Widow | 4 | 8.0 | 5 | 10.0 | 9 | 9.0 | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Divorced | 2 | 4.0 | 1 | 2.0 | 3 | 3.0 | |
| **•Occupation:** | | | | | | | |
| **A) Medical proffesion related job:** | 7 | 14.0 | 12 | 24.0 | 19 | 19.0 | 0.326 |
| Technician | 2 | 4.0 | 5 | 10.0 | 7 | 7.0 | 0.568 |
| Worker | 5 | 10.0 | 7 | 14.0 | 12 | 12.0 | |
| **B) Non-medical proffesion related job:** | 43 | 86.0 | 38 | 76.0 | 81 | 81.0 | 9.175<br>0.027* |
| Unskilled work | 0 | 0 | 4 | 8.0 | 4 | 4.0 | |
| Free work | 2 | 4.0 | 6 | 12.0 | 8 | 8.0 | |
| Not working | 10 | 20.0 | 10 | 20.0 | 20 | 20.0 | |
| Agriculture engineer | 31 | 62.0 | 18 | 36.0 | 49 | 49.0 | |
| **•Education:** | | | | | | | |
| Illiterate | 11 | 22.0 | 11 | 22.0 | 22 | 22.0 | 0.606 |
| Read & write and primary | 22 | 44.0 | 24 | 48.0 | 46 | 46.0 | 0.962 |
| Preparatory educ. | 8 | 16.0 | 6 | 12.0 | 14 | 28.0 | |
| Secondary educ. | 4 | 8.0 | 3 | 6.0 | 7 | 14.0 | |
| High educ. | 5 | 10.0 | 6 | 12.0 | 11 | 22.0 | |

***Significant (P<0.05)**

***Table (II) : Medical data of the participants (n=100).***

| **Categories** | **The participants (n=100)** | | | | | | |
|---|---|---|---|---|---|---|---|
| | **Studied participants (n=50)** | | **Control participants (n=50)** | | **Total (n=100)** | | **$\chi^2$ P** |
| | **n** | **%** | **n** | **%** | **n** | **%** | |
| **•Laboratory investigations:** | | | | | | | |
| **Albumin:** | | | | | | | |
| Normal | 48 | 96.0 | 40 | 80.0 | 88 | 88.0 | 6.051 |
| | | | | | | | |
| **Bilirubin:** | | | | | | | |
| Normal | 41 | 82.0 | 40 | 80.0 | 81 | 81.0 | 0.065 |
| | | | | | | | |
| **Prothrombin time:** | | | | | | | |
| Normal | 39 | 78.0 | 34 | 68.0 | 73 | 73.0 | 1.268 |
| | | | | | | | |
| **SGOT:** | | | | | | | |
| Normal | 44 | 88.0 | 37 | 74.0 | 81 | 81.0 | 3.184 |
| | | | | | | | |
| **SGPT:** | | | | | | | |
| Normal | 44 | 88.0 | 37 | 74.0 | 81 | 81.0 | 3.184 |
| | | | | | | | |

***Table (III): Medical data of family history of the participants (n=100).***

| **Categories** | **The participants (n=100)** | | | | | | |
|---|---|---|---|---|---|---|---|
| | **Studied participants (n=50)** | | **Control participants (n=50)** | | **Total (n=100)** | | **$\chi^2$ P** |
| | **n** | **%** | **n** | **%** | **n** | **%** | |
| **• Family history:** | | | | | | | |
| +Ve | 24 | 48.0 | 19 | 38.0 | 43 | 43.0 | 1.020 |
| -Ve | 26 | 52.0 | 31 | 62.0 | 57 | 57.0 | 0.313 |
| **Degree of relation (n=+ve):** | | | | | | | |
| First degree | 21 | 87.5 | 13 | 68.4 | 34 | 79.1 | 2.535 |
| Second degree | 1 | 4.2 | 3 | 15.8 | 4 | 9.3 | 0.282 |
| Third degree | 2 | 8.3 | 3 | 15.8 | 5 | 11.6 | |
| **- HCV detection:** | | | | | | | |
| Accidentally due to an other health problem | 29 | 58.0 | 36 | 72.0 | 65 | 65.0 | |
| Blood screening for traveling abroad | 21 | 42.0 | 12 | 24.0 | 33 | 33.0 | 5.208<br>0.074 |
| | | | | | | | |
| Signs / symptoms of liver disease | 0 | 0 | #2 | 4.0 | 2 | 2.0 | |

#Two patients had complain of abdominal pain**.**

***Table IV: Comparing mean scores of quality of life domains pre &one month post implementing educational program among the participants* (studied and control groups) (n=100). *(n=100)*.**

| Quality of life domain | Pre- educational program | | | | post- educational program | | | |
|---|---|---|---|---|---|---|---|---|
| | **Studied participants** | **Control participants** | **t-test** | **p** | **Studied participants** | **Control participants** | **t-test** | **p** |
| | Mean±SD | Mean±SD | | | Mean±SD | Mean±SD | | |
| • Physical functioning | 23.96±1. 83 | 23.90±1.62 | 0.174 | 0.862 | 26.48±1.88 | 24.86±1.81 | 4.384 | 0.0001* |
| | | | | | | | | |
| • Role limitation due to physical problems | 11.86±2.39 | 11.90±2.48 | 0.082 | 0.935 | 11.88±1.91 | 11.44±2.17 | 1.076 | 0.285 |
| • Pain | 8.98±0.94 | 8.84±1.13 | 0.674 | 0.502 | 12.04±2.33 | 9.40±1.34 | 6.946 | 0.0001* |
| • Health perception | 12.74±1.96 | 12.90±2.04 | 0.400 | 0.690 | 17.18±2.80 | 14.02±2.10 | 6.384 | 0.0001* |
| • Vitality | 6.92±1.32 | 6.74±1.29 | 0.689 | 0.493 | 8.50±1.55 | 7.06±1.48 | 4.748 | 0.0001* |
| • Social function | 6.46±1.34 | 6.46±1.26 | 0.000 | 1.000 | 7.54±1.18 | 6.74±1.14 | 3.446 | 0.0001* |
| • Role limitations due to emotional problems: | 3.30±1.26 | 3.50±1.28 | 0.785 | 0.434 | 3.92±0.92 | 3.64±1.22 | 1.291 | 0.200 |
| • Mental health | 15.60±2.39 | 15.70±1.90 | 0.232 | 0.817 | 19.44±2.34 | 18.48±1.91 | 6.931 | 0.0001* |
| **Total QOL scores** | **85.40±3.50** | **85.32±3.94** | **0.107** | **0.915** | **102.14±4.79** | **90.00±4.81** | **12.640** | **0.0001*** |

***Significant (P<0.05)**

## V. Discussion

In the middle East, it has been well documented that, Egypt has higher rates of HCV than other countries. [29] According to the results of this study, Most participating patients were males, this is can be explained that, male were more high risk for getting hepatitis C infection from barber shop through interaction with a contaminated instrument. Furthermore, most patients in both the studied and control group were working in agriculture field. This in line with Frank et al., (2000)[30]. who illustrated that, campaigns of the antischistosomal treatment which implemented from the 1950s through the 1980s; was largely attributed to spreading HCV infection throughout Egypt. This also agrees with Mostafa et al., (2010) [31] , Elgharably et al., (2017) [32] . and Mohamed et al., (2013). [8] who mentioned that, the patient's history of antischistosomal injection treatment is the risk factor for HCV transmission that specifically sets Egypt apart from other countries.

In the present study, it was found that, nearly half of the participants in both the studied and control group had a family history of hepatitis C, mostly in the very close family members (first degree relations). This is in the line with a research conducted by Reker C& Islam K. (2014) [33] which found that, contaminatted medical procedures and unsafe familial practices are the main risk factors for HCV transmission. Therefore , implementation of HCV preventive measures, will help to decrease the prevalence of the disease.

The results also found that, in more than half of the participants detected their disease accidentally through their medical screening for another health problem or for traveling abroad. This is also agrees with **Denniston et al., (2008)** [15] . who found that, in their study, less than fifty percent of the hepatitis C patients, had not heard about the disease before their blood tests were positive. Furthermore they illustrated that, a number of patients remain unaware of their illness, unless they develop liver-related complications and have to undergo extensive therapy as a result. This further shows the importance of educational programs to raise patient's awareness about the disease and its management.

The results of the present study revealed that, the patients in the study group, before receiving education, scored low to moderate quality of life level. However, after one month of receiving the educational program, the patients' mean scores of the quality of life level, improved. On the other hand, quality of life scores for patients in the control group remained moderate to low as there was no educational program intervention in this group. These results are also in line with the research conducted by ***Zandi et al (2005)*** [16] which also revealed a positive effect on all HRQoL aspects, particular in the emotional impact on the patient as well as their ability to conduct social relationships and commitments. In addition, the mental health as well as the ability to perform physical activities improved significantly after the education program intervention. ***Ghany et al (2009)*** [34] also recommend that, it is very important that the doctors and caregivers keep the patients

informed of the side-effects and the possible outcomes of the treatments. This is also agrees with the results of the present study which suggests that, the patients, at all time, should be informed about how they can overcome the negative side-effects of the treatment and lead as normal life as possible.[35] Furthermore, these results are also in line with the research conducted by ***Cacoub et al (2008)***[14] which was very similar to the present study. It was revealed that, patient education is very important in the real-life setting, for patients being treated with Ribavirin and Pegylated Interferon is not just the patients' acceptance of the treatment but also in their willingness to continue the treatment once the negative side-effects set in. like the present study, their research also suggests the positive impact of education program on patient quality of life and outcome.

## VI. Conclusion

In conclusion, this study demonstrated that, applied health education have positive effect on HRoQL of hepatitis C patients treated by Pegylated Interferon with Ribavirin.

## VII. Recommendation

Introduction of the structured booklet to every patient undergoing antiviral therapy by Pegylated Interferon plus Ribavirin. Further researches of an educational programs along with long-term follow up are suggested.

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