

EFFECT OF IMPLEMENTING EARLY PALLIATIVE CARE ON HEPATOCELLULAR CARCINOMA PATIENTS' OUTCOMES

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ABSTRACT

Background: Hepatocellular carcinoma is the world's fifth most common cancer and the second biggest cause of cancer-related death. HCC patients encounter a wide range of symptoms that are severe enough to affect their quality of life. Nurses must develop collaborative, multidisciplinary symptom treatment strategies. **Aim:** Evaluate the effect of implementing early palliative care on hepatocellular carcinoma patients' outcomes. **Subjects and method: design:** Quasi-experimental design was utilized. **Subjects:** proposed Sample of 114 adult patients aged 20 - 60 years old of both sexes who diagnosed of hepatocellular carcinoma. The research was carried out in both inpatient and outpatient clinics for patients follow up at Mahalla Hepatology Educational Hospital affiliated to Ministry of Health. **Tools:** Four tools were used for the collection of the necessary data and achieving the aim of the study as follows; Interview questionnaire sheet, FACT-Hep Version4, ESAS, CES-Dep. **Results:** Revealed that there was significant improving effect regarding total score of FACT-Hep, ESAS, and CES-Dep two weeks post implementation of early palliative care and in follow up. **Conclusion:** The study concluded that the early palliative care improves the quality of life, relieves pain and other symptoms either from the disease or from the treatment and improves mood in patients with hepatocellular carcinoma. **Recommendations:** Early palliative care should be initiated early once the patient diagnosed in order to be integrated with medical treatment. This research has provided a starting point for further studies regarding health services research in palliative care.

Key Words: Early palliative care, Hepatocellular carcinoma, patients' outcomes

INTRODUCTION

Hepatocellular carcinoma is the 5th frequent malignancy worldwide. Hepatocellular carcinoma (HCC) has risen in incidence and prevalence in recent years, and it is now the second leading cause of cancer death worldwide. Hepatitis B and C virus infections, as well as alcoholic cirrhosis, are important etiologies (*Kaiser et al., 2014*). HCC is a major public health issue in Egypt. Liver cancer is the most prevalent cancer in men and the second most common cancer in women, according to numerous Egyptian regional registries (*Baghdady et al., 2014*).

Hepatocellular carcinoma patients may experience weight loss, a lack of appetite, or early stomach fullness, as well as a noticeable mass in the upper abdomen, right upper quadrant pain, a palpable mass, anorexia, or cachexia. Furthermore, biliary tree obstruction can cause jaundice, tumor necrosis can cause fever, and metastatic HCC lesions might cause bone ache. In addition, advanced hepatobiliary cancers can cause extreme weakness, fatigue, and depression due to pronounced energy depletion and muscle wasting (*Attwa et al., 2015*).

Patients' function and quality of life (QoL) rapidly deteriorate as a result of multiple symptom occurrences, as well as an increase in morbidity and death. Hepatobiliary cancer patients are vulnerable to disease and treatment-related problems, This may have a detrimental impact on overall life quality. Treatment techniques frequently increase post-treatment morbidity and symptom load while having little or no effect on survival (*Bai & Lazenby, 2015*).

Patients with HCC have many worries, concerns, and questions about the disease and treatment options when they are diagnosed. Nurses assist patients by educating them, providing assistance, and serving as advocates for them. For patients receiving HCC treatment, expert nursing care is critical. The amount of technical nursing care needed is determined by the treatment (*Fan et al., 2010*).

Although improving patient quality of life and any supportive care intervention must have the goal of minimizing symptom burden, palliative care is more than just symptom management. Early PC integration has been shown to improve patients' QOL and mood, and also has positive effects on patient outcomes. The early integrated PC in also has the benefit of strengthening patients' ability to cope with their prognosis and improving their communication with professionals about their treatment preferences (*Temel et al., 2017*).

AIM OF THE STUDY

The study aims to evaluate the effect of implementing early palliative care on hepatocellular carcinoma patients' outcomes.

Research hypothesis:

- Study group will experience better quality of life than control group.
- Study group will have less symptoms intensity than control group.
- Study group will have improved mood than patients in control group.

Operational Definitions:

The following terms was operationally defined as follows, for the purpose of the study:

Patient's outcomes means: Patient's quality of life, Patient's intensity of symptoms, Patient's mood.

Early palliative care: Palliative care which introduced early once the patient diagnosed with the disease of hepatocellular carcinoma and integrated on the same line with the medical treatment which the patient received.

SUBJECTS AND METHOD

Design: The current study's goal was met using a quasi-experimental research approach.

Setting: This study was conducted in Mahalla Hepatology Educational Hospital, El Mahalla AlKoubra in the inpatient department as well as outpatient clinics for patients follow up.

Subjects: A proposed Sample of 114 adult patients aged 20 - 60 years old of both sexes who admitted to the previously mentioned setting with the diagnosis of hepatocellular carcinoma were recruited for the participation in the current study. The total study sample was randomly assigned to two equals groups; study and control; study group: composed of 57 adult patients receiving the routine hospital in addition to palliative care as developed by the researcher and control group: composed of 57 adult patients receiving their usual hospital routine care.

Sample Size = 57 for each group was calculated according to this equation

$$n = (z_{1-\alpha/2} + z_{1-\beta})^2 \frac{\sigma^2}{\Delta^2}$$

$$n = \frac{(z_{1-\alpha/2} + z_{1-\beta})^2 \sigma^2}{\Delta^2}$$

$$\Delta^2 = \frac{\sigma_1^2}{n_1} + \frac{\sigma_2^2}{n_2}$$

Description:

n=required sample size.

$Z_{1-\alpha/2}$ = Desired level of statistical significance =1.96when $\alpha =5\%$ for two-sided test.

$z_{1-\beta}$ = Desired power for 85% power

σ = Standard deviation of the outcome variable

$d^2 = d$ = Expected difference to be detected

Criteria for selection of the subjects:

A) Inclusion criteria: The patients in the above mentioned setting were selected and included in the study according to the following criteria: Male or female patients 20 - 60 years of age, Early Diagnosis of hepatocellular carcinoma in stage 0 (very early stage), stage A, stage B and early diagnosed stage C according to Barcelona-Clinic Liver Cancer (BCLC) staging classification, Willing to participate in the study, Conscious, able to comprehend, communicate and cooperate with the care.

B) Exclusion criteria: Pregnant or breastfeeding patients, Active clinically serious infections.

Tools of data collection: The following four tools were used to collect the necessary data and achieve the study's goal:

Tool I: Interview questionnaire: The researcher created this tool to acquire the essential bio sociodemographic and assess the medical data of the patient.

Part 1: Bio sociodemographic data of the study sample included: age, sex, marital status, level of education and occupation.

Part 2: Medical data: This part was introduced to assess the date of admission, chief complaints, the family history of hepatocellular carcinoma or history of any type of cancer and patient exposure to any risk factor for hepatocellular carcinoma (*Klein et al., 2015*).

Tool II: The Functional Assessment of Cancer Therapy- Hepatobiliary (FACT-Hep) scale is a self-report questionnaire designed to assess health-related quality of life (HRQoL) in hepatobiliary cancer patients (*Maltoni et al., 2016; Cella et al., 2013*). The FACT-Hep is made up of 45 items; including a 27-item FACT-general (FACT-G) subscale

and an 18-item hepatobiliary-specific subscale that, forming the FACT-Hep (*Cella et al., 2013*) with maximum score 180 (*Soliman et al., 2013; Janda et al., 2017*). Higher ratings indicate a higher quality of life. The FACT-test-retest Hep's correlation range was reported to be 0.84 to 0.91. Cronbach's alpha was 0.93, indicating a high level of internal consistency (*Janda et al., 2017*). The Arabic version was used after obtaining an approval (*Cella, 2017*).

FACT-Hep scoring: The higher the score on all FACT scales and symptom indices, the better the QOL. The sum of the FACT-G (the first four subscales common to practically all scales) plus the "Additional Concerns" subscale yields the total score for each FACT scale (*Singh et al., 2013; Turnbull et al., 2010*).

Tools III: The Edmonton Symptom Assessment Scale (ESAS) is a self-reported questionnaire that has been developed and validated to measure symptom intensity (*Chasen et al., 2015*). The ESAS is a numerical scale that measures nine fundamental symptoms (pain, exhaustion, nausea, depression, anxiety, sleepiness, appetite, sensation of wellbeing, and shortness of breath) (range, 0-10). The scale runs from 0 to 900, with higher values indicating more severe symptoms (*Watanabe et al., 2011; Ferrell et al., 2017*).

The ESAS was reported to have a test-retest correlation range of (0.57–0.94). Cronbach's alpha was 0.72, indicating a high level of internal consistency (*Dong et al., 2015*). The researcher translated it into Arabic.

Scoring ESAS: On a scale of 0 to 10, the patient should rate the severity of each symptom, with 0 indicating no symptom and 10 indicating the worst possible severity (*Nekolaichuk et al., 2019*).

Tool IV: Epidemiological Research Center Depression Scale (CES-D) was used to evaluate depression symptoms. The CES-D is a questionnaire that asks about depressive symptoms over the previous seven days and is commonly used in epidemiological research of depression. Scores vary from 0 to 60, with a score of 16 or higher indicating severe depression (*Moore et al., 2011*). The researcher translated it into Arabic.

Administrative preparations

- The general director of Mahalla Hepatology Educational Hospital received an official letter from Mansoura Faculty of Nursing, El Mahalla AlKoubra to carry out the study after offering an overview of the study's nature and objectives.
- Patients who agreed to participate in the trial after being told about the goal and nature of the investigation signed an informed written permission form.
- All tools were tested for clarity and visibility on the subjects suffering from hepatocellular carcinoma.

A **pilot study** was carried out on 10% (12) of the patients, who were chosen at random. Patients who took part in the pilot study were not included in the final study. The purpose of the pilot study was to estimate the time required to complete the questionnaire sheet, as well as to assess the practicality, objectivity, clarity, and applicability of the study tools, as well as to identify any challenges that may arise during the study's implementation. The data obtained from the pilot study were analyzed manually. Each sheet lasted about 20-25 minutes to be filled.

Data collection

Patients who fulfilled the previously mentioned study criteria, attending the study settings and agreed to participate in the study were selected randomly and assigned equally to study and control groups.

Data collection phases

The study was implementing through the following four phases:

a) Assessment phase: Data from both groups were collected in the inpatient department in the hospital and follow up was continued in hepatocellular carcinoma outpatient clinic. Hepatocellular carcinoma clinic were visited twice weekly. Each patient was interviewed individually by the researcher before applying the planned palliative care in order to collect the baseline patient's data (pre-intervention) using all study tools. The researcher was assessing the needs of each patient to consider it when preparing the palliative care and teaching booklet. Confidentiality for all collected information was strictly assured.

b)Phase 2: palliative care development Based on the data achieved from first assessment and review of literature, the researcher adapted the palliative care depend on **(The National Consensus Project for Quality Palliative Care Clinical Practice Guidelines for Quality Palliative Care 4rd edition 2013)** according to patients and families' needs and preferences. The palliative care was designed. Its main was to improve the quality of life of the patients who are diagnosed of hepatocellular carcinoma according to inclusion criteria, at early time from being diagnosed, decrease their intensity of symptoms accompanied with disease progression and treatment and maintain their psychological health post implementing palliative care.

An illustrated colored booklet about early palliative care was designed by the researcher to be delivered to each participant in the research in the implementation phase which covered the care of the problems reported by the patients who were interviewed. It was planned for each patient in a simple, easily understandable Arabic form according to each patient needs and level of education.

c) Phase 3: Palliative care implementation:

The control group received the routine hospital care only according to the disease and the hospital rules. The study group received the routine hospital in addition to the palliative care designed for this study. The palliative care was conducted during the patient's hospital stay (3-5 days). At the beginning, an orientation to the aim of the study and the goal of implemented care took place. In addition, the researcher stressed on the importance of follow up and active participation. The researcher used simple, brief and clear words and using a very slang language that suits the level of patients without ignoring motivations, positive reinforcement and emotional encouragement.

An instructional booklet was given as a reward for each patient to draw his or her attention, excite him or her, and encourage practice at home with the intention of using it as a future reference, motivate him or her and support practice at home using it in the future reference. At the end of interview (30-45 minute), a brief summary was given by the researcher. Patients were allowed to ask any interpretations, elaboration or explanation.

Encourage the patients and their caregiver to attend weekly follow up. All patients were given contact information for the researcher and the number for the 24-hour on-call for asking questions and reassurance. Patients were encouraged to call if their

symptoms are poorly controlled. Periodically, the researcher was calling the patients to be ensured that the patients were following the instructions, reassure, answer the patient questions and ascertain patient adherence to the care and instructional booklet.

d) Phase 4: Evaluation

The final phase of data collection is evaluating the patient's response to the proposed care and the extent to which the outcomes have been achieved. The patients were evaluated three times using the study tools; immediately on admission using all the study tools for both groups, the second was done after 2 weeks after discharge and the third (follow up) was conducted after one month of the second phase.

Ethical consideration: During this study, all ethical considerations were taken into account, including receiving approval from Mansoura University's Faculty of Nursing to perform the study. After explaining the study's goal to the study participants, they signed an informed written consent form before being included in the study. The researcher emphasized that the privacy and the confidentiality of all information were secured by coding the data. The researcher emphasized that participation in the study was entirely voluntary and anonymity. Each patient was told that refusing to participate in the study or withdrawing would have no negative consequences and would not affect their care. Finally, all participants received professional assistance and necessary guidance as needed, and the researcher's telephone number was given to all patients in the study and control groups to answer their questions. In addition, an instruction manual booklet was provided to the control group after evaluation to fulfill the ethical considerations of the study.

IV). Statistical Design

SPSS for Windows version 20.0 was used for all statistical analyses (SPSS, Chicago, IL). The mean and standard deviation of all continuous data were calculated using a normal distribution (SD). Numbers and percentages were used to express categorical data. Student's t test was used to compare two variables with continuous data, while the chi-square test was used to compare variables with categorical data. The correlation coefficient test is used to determine whether two variables with continuous data are correlated. The threshold for statistical significance was set at $p < 0.05$.

RESULTS:

Table (1): confirmed that no statistically significant differences were observed between the two groups regarding their sociodemographic characteristics ($P>0.05$).

Table (2): showed that no statistically significant differences were found between the patients in both groups regarding their medical data ($P>0.05$).

Table (3): illustrated no statistically significant differences were observed between the two groups at pre intervention regarding FACT-Hep including Physical, Social, Emotional, Functional, Hep-concern wellbeing and total FACT-Hep score ($P>0.05$). There were no statistically significant differences were observed between the two groups regarding ESAS at pre-intervention, including pain, tiredness, drowsiness, nausea, lack of appetite, dyspnea, depression, anxiety, best wellbeing and total ESAS score ($P>0.05$). In addition, this table illustrated that there were no statistically significant differences were observed between the two groups regarding CES-Dep at pre intervention ($P>0.05$).

Table (4): showed that there were highly significant differences between study and control groups regarding FACT-Hep two weeks post implementations of early palliative care, including Physical, Social, Functional, Hep-concern wellbeing and total FACT-Hep score ($P<0.001$), except Emotional wellbeing ($P=0.214$). Also, it showed that there was highly significant differences in the study group in comparison to control group regarding ESAS two weeks post implementations of early palliative care, including tiredness, drowsiness, nausea, lack of appetite, dyspnea, depression, best wellbeing and total ESAS score ($P>0.05$), except Pain and Anxiety ($P>0.05$). Concerning CES-Dep Scale, it clarified that between the study and control groups, there were very statistically significant differences two weeks post implementations of early palliative care regarding total score of CES-Dep Scale (19.1 ± 4.3 and 21.6 ± 5.7) in the study and control group, respectively ($p<0.05$).

Table (5): showed that There was highly significant differences between study and control groups regarding FACT-Hep at follow up one month post implementations of early palliative care, including Physical, Social, Emotional, Functional, Hep-concern wellbeing and total FACT-Hep score ($P<0.001$). Also, it showed that there were highly significant differences in the study group in comparison to control group regarding ESAS Scale at follow up one month post intervention of implementations of early palliative care, including pain, tiredness, drowsiness, nausea, lack of appetite, dyspnea, depression,

anxiety, best wellbeing and total ESAS score ($P < 0.001$). Concerning CES-Dep scale, this table indicates the differences between the study and control groups were highly statistically significant at follow up one-month post intervention of implementations of early palliative care regarding total score of CES-Dep Scale ($p < 0.001$).

Table (6): regarding pre-intervention, this table reveals highly significant correlations between FACT-HEP, ESAS and Depression at pre-intervention ($p < 0.05$). Concerning post intervention This tables reveals highly significant correlations between FACT-HEP, ESAS and Depression at follow up one-month post intervention in the study group ($p < 0.05$).

Figure (1): this figure clarifies that ESAS directly correlated with CES-Dep scale two weeks post intervention in the study group ($p < 0.001$), ($r = 0.586$) which reveals direct correlation between intensity of symptoms and depression at pre intervention.

Figure (2): This figure showed that ESAS directly correlated with CES-Dep scale at follow up one-month post intervention in the study group ($p < 0.001$), ($r = 0.592$) which reveals direct correlation between intensity of symptoms and depression at follow up one-month post intervention.

Table (1): Sociodemographic characteristics of the study and the control groups

	Intervention group		Control group		Chi square test	
	N	%	N	%	X ²	p
Age (years)						
20 – 30	0	0	0	0	1.213	0.271
31 – 40	0	0	0	0		
41 – 50	16	28.1	11	19.3		
51 – 60	41	71.9	46	80.7		
Sex						
Male	41	71.9	36	63.2	1.000	0.317
Female	16	28.1	21	36.8		
Marital status						
Single	25	43.9	19	33.3	1.427	0.490
Married	27	47.4	31	54.4		
Widow	5	8.8	7	12.3		
Educational level						
Illiterate	21	36.8	24	42.1	0.473	0.925
Primary	18	31.6	18	31.6		
Secondary	12	21.1	10	17.5		
University	6	10.5	5	8.8		
Occupation						
Not working	16	28.1	20	35.1	3.867	0.145
Governmental Work	8	14.0	14	24.6		
Private worked	33	57.9	23	40.4		

Table (2): Medical data between the study and the control groups

	Study group		Control group		Chi square test	
	N	%	N	%	X ²	P
Chief complaint						
Abdominal pain	56	98.2	55	96.5	0.342	0.558
Constipation	24	42.1	16	28.1	2.465	0.116
Dyspnea	9	15.8	4	7.0	2.171	0.141
Ascites	23	40.4	30	52.6	1.728	0.189
Anemia	42	73.7	35	61.4	1.961	0.161
Jaundice	52	91.2	46	80.7	2.617	0.106
Vomiting	9	15.8	10	17.5	0.063	0.802
Edema	7	12.3	5	8.8	0.373	0.542
Family history of cancer						
No	53	93.0	55	96.5	3.370	0.185
Cancer liver	1	1.8	2	3.5		
Other cancer	3	5.3	0	0.0		
Risk factors						
Heavy smoking	26	45.6	19	33.3	1.799	0.180
Obesity	23	40.4	16	28.1	1.910	0.167
HCV	55	96.5	55	96.5	0	1.000
HBV	10	17.5	5	8.8	1.919	0.166
Liver cirrhosis	57	100.0	57	100.0	0	1.000
Medical treatment						
Microwave ablation	22	38.6	18	31.6	1.015	0.602
Radiofrequency ablation	11	19.3	15	26.3		
TACE	24	42.1	24	42.1		

Table (3): Comparison of FACT-Hep, ESAS and CES-Dep scales between the study and the control groups at pre-intervention

	Study group	Control group	Student's t test	
	Mean \pm SD	Mean \pm SD	T	P
FACT-Hep				
Physical well-being	8.2 \pm 2.6	9.3 \pm 4.6	1.554	0.123
Social well-being	22.6 \pm 3.5	22.5 \pm 3.1	0.197	0.844
Emotional well-being	7.6 \pm 1.3	8.2 \pm 2.9	1.456	0.148
Functional well-being	16.5 \pm 2.0	15.6 \pm 3.5	1.674	0.097
Hep-Concern well-being	19.9 \pm 3.0	21.1 \pm 6.1	1.317	0.191
Total FACT-HEP score	74.9 \pm4.5	76.8 \pm8.8	1.451	0.149
ESAS				
Pain	7.1 \pm 1.4	7.3 \pm 1.1	0.756	0.451
Tiredness	6.3 \pm 3.0	6.1 \pm 2.1	0.578	0.565
Drowsiness	5.1 \pm 2.0	4.6 \pm 1.6	1.528	0.129
Nausea	5.0 \pm 2.2	4.8 \pm 1.2	0.566	0.572
Lack of appetite	6.3 \pm 3.1	6.1 \pm 1.7	0.369	0.713
Dyspnea	5.5 \pm 2.7	6.0 \pm 1.7	1.128	0.262
Depression	6.2 \pm 2.3	5.9 \pm 1.9	0.808	0.421
Anxiety	7.3 \pm 1.5	7.4 \pm 1.5	0.431	0.667
Best wellbeing	6.4 \pm 3.2	6.3 \pm 1.2	0.192	0.848
Total ESAS Score	54.9 \pm12.3	54.5 \pm11.2	0.182	0.856
(CES-Dep) scale				
Total (CES-Dep) Score	31.3 \pm7.2	29.8 \pm9.1	0.972*	0.333

*significant P value ($P \leq 0.05$), * t value, Student's t test

Table (4): Comparison of FACT-Hep, ESAS and CES-Dep scales between the study and the control groups two Weeks Post Intervention

	Study group	Control group	Student's t test	
	Mean \pm SD	Mean \pm SD	T	P
FACT-Hep				
Physical well-being	13.8 \pm 2.3	11.2 \pm 2.4	5.838	<0.001*
Social well-being	22.5 \pm 3.9	19.1 \pm 3.3	5.013	<0.001*
Emotional well-being	11.4 \pm 2.2	10.8 \pm 2.7	1.251	0.214
Functional well-being	16.2 \pm 2.9	12.0 \pm 4.0	6.366	<0.001*
Hep-Concern well-being	29.5 \pm 3.4	24.9 \pm 4.3	6.303	<0.001*
Total FACT-HEP score	93.3 \pm6.9	78.1 \pm5.5	10.959	<0.001*
ESAS				
Pain	4.30 \pm 1.4	4.54 \pm 0.9	1.077	0.284
Tiredness	4.26 \pm 2.0	4.89 \pm 1.2	2.059	0.042*
Drowsiness	1.54 \pm 0.7	2.58 \pm 1.3	5.318	<0.001*
Nausea	2.19 \pm 1.2	3.61 \pm 1.5	5.562	<0.001*
Lack of appetite	3.26 \pm 1.3	4.68 \pm 1.2	6.206	<0.001*
Dyspnea	1.88 \pm 0.9	2.75 \pm 1.3	4.154	<0.001*
Depression	2.81 \pm 1.4	3.53 \pm 1.7	2.468	0.015*
Anxiety	4.00 \pm 1.3	4.02 \pm 1.6	0.066	0.947
Best wellbeing	4.07 \pm 2.2	4.86 \pm 1.4	2.311	0.023*
Total ESAS Score	28.3 \pm6.7	35.5 \pm8.9	4.859	<0.001*
(CES-Dep) Scale				
Total (CES-Dep) Score	19.1 \pm4.3	21.6 \pm5.7	2.573	0.011*

*significant P value ($P \leq 0.05$), * t value, Student's t test

Table (5): Comparison of FACT-Hep, ESAS and CES-Dep scales between the study and the control groups at Follow up One Month Post Intervention

	Study group	Control group	Student's t test	
	Mean \pm SD	Mean \pm SD	T	P
FACT-Hep				
Physical well-being	19.3 \pm 2.1	16.3 \pm 4.5	4.565	<0.001*
Social well-being	17.0 \pm 2.9	13.2 \pm 5.9	4.354	<0.001*
Emotional well-being	18.5 \pm 2.7	14.8 \pm 3.6	6.289	<0.001*
Functional well-being	12.6 \pm 4.2	9.8 \pm 4.7	3.354	<0.001*
Hep-Concerns	42.5 \pm 4.2	36.7 \pm 5.6	6.264	<0.001*
Total FACT-HEP score	110.0 \pm8.3	90.8 \pm7.6	12.921	<0.001*
ESAS				
Pain	3.11 \pm 0.8	6.96 \pm 1.5	17.387	<0.001*
Tiredness	4.46 \pm 1.2	8.51 \pm 1.8	14.135	<0.001*
Drowsiness	1.10 \pm 0.5	4.28 \pm 2.2	10.642	<0.001*
Nausea	1.82 \pm 0.9	5.60 \pm 2.7	10.027	<0.001*
Lack of appetite	2.68 \pm 1.3	8.33 \pm 1.8	19.212	<0.001*
Dyspnea	3.19 \pm 0.6	5.63 \pm 2.8	8.960	<0.001*
Depression	2.44 \pm 1.1	5.91 \pm 2.2	10.651	<0.001*
Anxiety	2.51 \pm 0.8	6.40 \pm 1.9	13.974	<0.001*
Best wellbeing	3.91 \pm 1.1	8.46 \pm 1.8	16.023	<0.001*
Total ESAS Score	25.22 \pm4.8	60.08 \pm12.3	19.933	<0.001*
(CES-Dep) scale				
Total CES-Dep Score	15.3 \pm1.5	25.4 \pm4.9	14.792	<0.001*

*significant P value ($P \leq 0.05$), * t value, Student's t test

Table(6): Statistical Correlations between the Total Scores of FACT-HEP, ESAS and Depression in the Study Group Pre-Intervention and post intervention

	FACT-FEP score		ESAS score		(CES-Dep)	
	R	P	R	p	r	P
Pre-Intervention						
FACT-FEP score			-0.424	<0.001*	-0.272	0.041*
ESAS score	-0.424	<0.001*			0.554	<0.001*
Post intervention						
CES-Dep score	-0.272	0.041*	0.554	<0.001*		
FACT-FEP score			-0.366	0.005*	-0.307	0.020*
ESAS score	-0.366	0.005*			0.592	<0.001*
CES-Dep score	-0.307	0.020*	0.592	<0.001*		

*significant P value ($P \leq 0.05$)

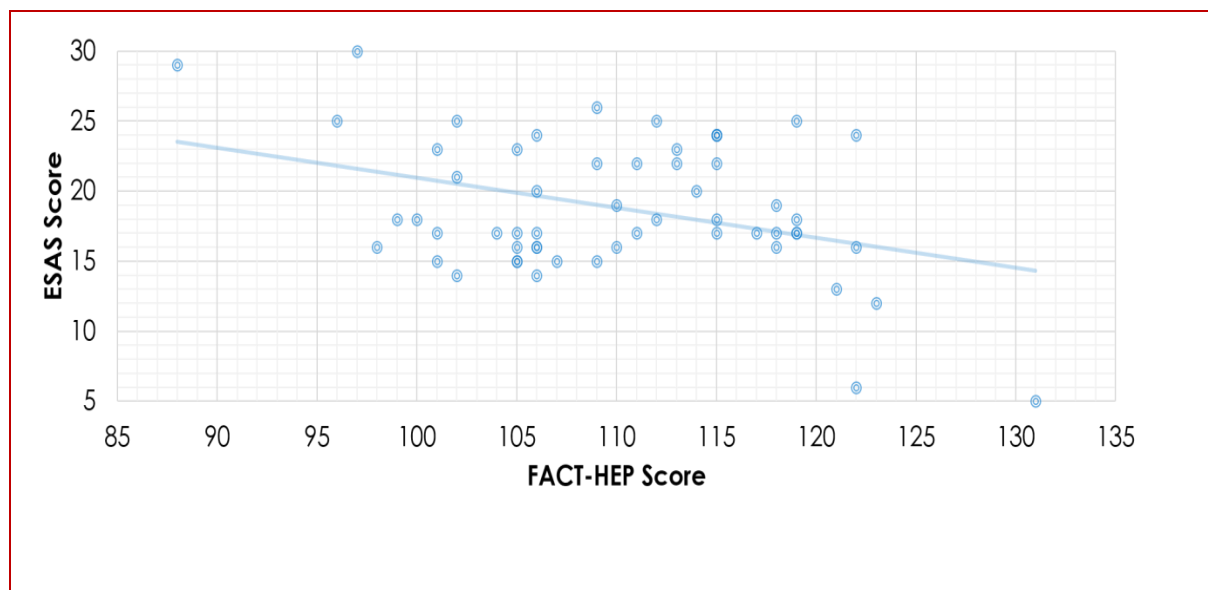


Figure 1. Correlation between the Total Scores of FACT-Hep and ESAS One-Month Post Intervention

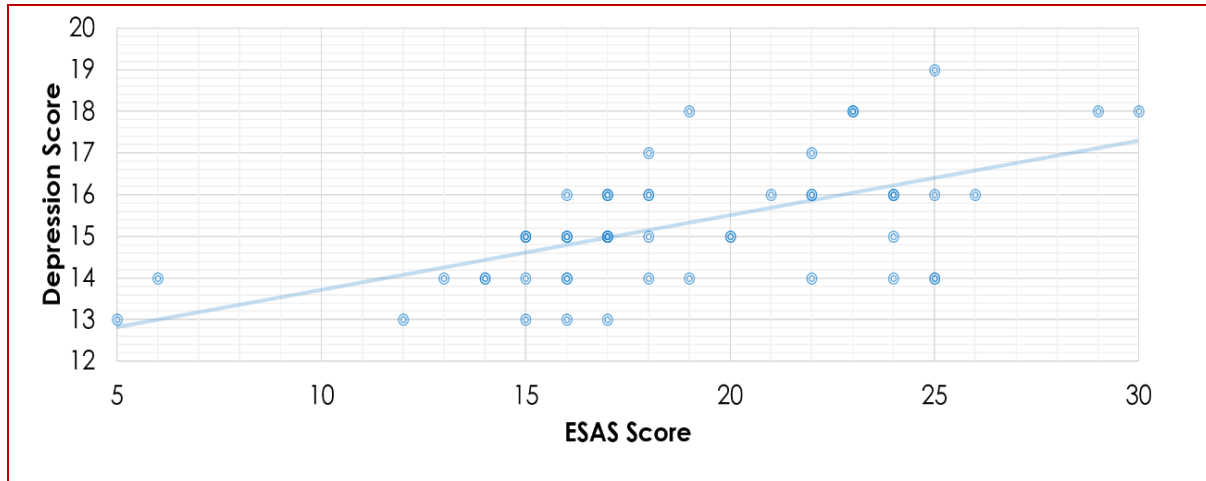


Figure 2. Correlation between the Total Scores of ESAS and CES-Dep One-Month Post Intervention

DISCUSSION

Hepatocellular carcinoma (HCC) is a feared liver disease complication with a low overall survival rate. Throughout the duration of the illness, patients are subjected to a variety of therapies. Patients face substantial uncertainty about care and prognosis due to the difficulty of the treatment algorithm. This population exhibits the effects of both end-stage liver disease and cancer since HCC occurs in the sense of underlying liver disease (*Woodrell et al., 2018*). Furthermore, because of physical symptoms and psychological distress, patients with end-stage liver disease undergo a predictable and progressive deterioration in their quality of life. EPCI (early palliative care intervention) is related to enhanced symptom management and mood (*Baumann et al., 2015*).

The main aim of the current study was to evaluate the effect of implementing early palliative care on hepatocellular carcinoma patients' outcomes. The findings of the current study were representing the following sequence:

In terms of socio-demographic parameters, no statistically significant differences were detected between the study and control groups. When it came to age, the study group and control group had the highest percentage of people between the ages of 51 and 60, and when it came to sex, males were more abundant in the study sample.

This is similar to study by *Subramaniam et al., (2013)*, who illustrated that the mean age of their studied participants was 54.26 years old with high prevalence between 51 and 60 years, and male to female ratio was 5:1 folds. Also, another study of the epidemiology of

HCC in Africa by **Kew, (2015)**, found that the southern African men were higher in incidence of the disease than women with mean age of 50.9 and 51.0 years respectively for both sex.

Concerning the marital status and the level of education, it was found that more than half of the studied participants of both groups were married and more than one third of them were illiterate. Similarly, a higher proportion of cases studied by **Phukan et al., (2018)** were illiterate (73.1%), also their mean age at interview was 54.7 years among the study group and 55.6 years in the control. Additionally, the illiterate group of a study by **Hossain et al., (2016)** was the top of the list represented about 40%, and the mean age was 48.78 years old and about 86% of patients were males and only 14% of them were females.

On completing the current study and regarding patients' medical data, it was observed that abdominal pain represented the highest proportion of the chief complaints followed by jaundice in both groups. It was also presented that the highest percentages of the patients reported that they didn't have family history of cancer. Furthermore, regarding the risk factors, all patients in the study and control groups had liver cirrhosis as the first risk factor followed by HCV. Also, two fifth of the patients were managed by TACE, followed by microwave ablation, and radiofrequency ablation in both groups.

According to a systematic study by **Christian-Miller et al., (2018)**, due to severe structural and functional alterations in the peripheral and central nerve systems, this may cause patients with chronic abdominal pain to suffer heightened pain perception, right upper quadrant abdominal pain is one of the most often documented symptoms in patients with HCC.

In a book entitled "Hepatocellular Carcinoma - Future Outlook" published by **Barghini et al., (2013)**, They hypothesized that jaundice is a common indicator of HCC presentation, and that it is present at the time of HCC diagnosis in 28% of African patients.

As a baseline of the study, no statistically significant differences were observed between the two studied groups at pre-intervention regarding FACT-Hep, ESAS, or CES-Depression. Similarly, a randomized controlled trial by **Ferrell et al., (2017)** showed no statistically significant changes in demographic or clinical features between the intervention and usual care groups at baseline.

Also, no significant differences were seen in baseline quality of life or mood symptoms between the studied group of the study by *Temel et al., (2010) and Temel et al., (2017)*. On the other hand, the results of a trial by *Zimmermann's et al., (2014)* revealed a baseline imbalance between the intervention and control groups, with the intervention group scoring better on outcome measures (for FACT at $P= 0.03$; for ESAS at $P<0.001$) in the intervention group.

On completing the recent study and firstly regarding the FACT-Hep score, it was shown that there were highly significant differences between study and control groups regarding FACT-Hep at two weeks post implementation of early palliative care, including whole FACT-Hep score items except emotional wellbeing. And at follow up at one-month post implementations, there were extremely significant differences among study and control groups including all items of the FACT-Hep score. From the researcher's point of view, that means that the palliative care had a great impact on quality of life in patients with hepatocellular carcinoma after two weeks.

In a similar way, *Krakauer, (2019) and Yang et al., (2015)* concluded that PC improves the quality of life for patients and their families dealing with life-threatening diseases, whether physical, psychosocial, or spiritual, by preventing and alleviating distress through early detection, proper evaluation, and treatment of pain and other problems, whether physical, psychosocial, or spiritual. On contrast, a trial of 461 patients with advanced cancer by *Zimmermann's et al., (2014)*, illustrated that When compared to standard cancer care, early referral to a palliative care team did not improve quality of life (as measured by the FACIT scale).

Secondly, concerning the ESAS score, it was detected that there were highly significant differences in the study group in comparison to control group at two weeks post implementation of early palliative care, including all items of the ESAS score ($P<0.001$) except pain and anxiety, Additionally, there were highly significant differences at follow up one-month post-implementation, including whole items of the ESAS score ($P<0.001$); from the researcher's point of view, that reveals an improvement effect of implementations of EPC on intensity of symptoms in patients with hepatocellular carcinoma.

This is in agreement with *Baumann's et al., (2015)* study, as they showed that early palliative care intervention (EPCI) had a great impact on patients' symptoms; at least one moderate-to-severe symptom (ESAS individual symptom score > 5) was experienced by

more than three-quarters of the study participants. The most common symptoms were fatigue, sleep disturbance, and pruritus, while dyspnea and myalgia were the least prevalent. Half of the initial moderate-to-severe symptoms improved markedly after EPCI. Patients' pruritus, anxiety, and hunger all improved by more than three points. Fatigue and well-being showed a smaller, but statistically significant, improvement (1.79 and 1.96 points, respectively). Pain, myalgia, sexual dysfunction, sleep disruption, and dyspnea all improved after EPCI, although not statistically significant improvements.

On the same line, the American Society of Clinical Oncology (ASCO) (2016) recommended integrating palliative care early in the disease trajectory alongside cancer-directed treatment. Despite strong endorsements and evidences of benefit, many patients with cancer lack access to PC. A growing body of evidence is now available to inform the key domains in the practice of palliative care including; symptom management, psychosocial care, communication, decision-making, and end-of-life care (*Smith et al., 2012; Hui & Bruera, 2016*).

Additionally, studies by *Bruera & Yennurajalingam, (2012)* have shown improved symptom control in patients with advanced cancer as a result of a palliative care consultation. In a recent study, they found that, at the first follow-up visit after the consultation, patients achieved significant improvements in most cancer-related symptoms. In another study by *Casarett et al., (2011)* patients admitted to palliative care had better symptom control than patients in routine venues of care (i.e., medical/surgical wards, critical care units, and nursing homes).

There are numerous reasons why palliative care is more capable of alleviating symptoms than normal oncology care, including the fact that PC teams do systematic symptom evaluations using standard methods such as ESAS and regularly document symptom distresses. Furthermore, PC teams do regular assessments of emotional distress, screenings for delirium, and screenings for risk factors for any other psychological symptoms in their patients (*Lamba et al., 2016*).

In accordance with the inclusion of a palliative-care team in oncological treatment, as explored by *Ferrell et al., (2017)*, QoL and mood were shown to be much better in the palliative-care group, despite symptom relief, quality of end-of-life care, and survival being comparable. Furthermore, *Bakitas et al., (2015)* found that QoL, symptom relief, and mood in the latest study didn't differ between the two groups. Additionally, PC was

connected to improvements in QoL and symptom burden after 1–3 months, according to *Bakitas et al., (2015)*.

The explanation for EPC's positive effect on overall survival has sparked a lot of debate. Some correlate it with the benefit of PC on QoL and depression as both characteristics have been shown to be correlated with overall survival. PC strategy may also facilitate a more appropriate decision-making process (*Maltoni et al., 2016*).

Thirdly, regarding the CES-Depression Scale, it was clarified that between the study and control groups, there were statistically significant differences at two weeks post implementations of early palliative care ($p < 0.05$). Also, at follow up one-month post intervention ($p < 0.001$), and that reveals an improvement effect of early palliative care on mood in patients with HCC and relieve patients' depressive symptoms. Similarly, the study by **Temel et al. (2017)** on individuals with lung cancer found that palliative treatment improved their QOL ($P = 0.048$).

In a randomized controlled trial by *Dionne-Odom et al., (2015)*, they investigated the advantages of early versus delayed palliative care for cancer patients' informal family carers and discovered that variations in depression scores benefited the early group. ($P = 0.02$).

In recent years, research on health-related quality of life in cancer patients has exploded, as patient outcomes, particularly HRQL, have become a top concern for cancer treatment decisions. Hepatobiliary malignancies, including HCC, have a poor prognosis and survival rate, especially in individuals diagnosed at a stage (*Gmür et al., (2018)*). Findings by *Maltoni et al., (2016)* were overwhelmingly in favour of the experimental group, including the primary goal of the study, which was increased QoL after 12 weeks.

According to the correlations between patients' outcomes in this study, highly significant correlations between quality of life, intensity of symptoms and depression at follow up one-month post intervention in the study group were detected. Regarding correlation between FACT-HEP and ESAS, it was found that FACT-Hep's total score was high significantly correlated inversely with ESAS total score at follow up one-month post intervention in the study group, that reveals an inversely correlation between quality of life and intensity of symptoms at follow up one-month post intervention.

The Spearman's Rho test of *Khalili-Parapary et al., (2017)*'s study revealed a high and inverse correlation between ESAS and FACT ($r = 0.74$, $P 0.001$). Because higher FACT scores indicated better performance and lower ESAS scores suggested less suffering in patients, the negative correlation between these two tools can validate the criterion validity of ESAS.

Finally, regarding correlation between ESAS and CES-DEP, it was found that ESAS directly correlated with CES-Dep scale at pre intervention in the study group which reveals direct correlation between intensity of symptoms and depression at pre intervention. Data demonstrate that providing palliative care services to advanced cancer patients improves their experiences significantly by prioritising symptom control, quality of life, and treatment planning (*Greer et al., 2013*).

A study by *Baumann et al., (2015)* clarified that there is a significant association between symptom load and the ability to ameliorate depression in HCC patients, and understanding this relationship will help clinicians better palliate such patients, according to the study. Also, *Cohen et al., (2016)* in a review stated that uncontrolled symptoms, particularly chronic some, may result in development of depression.

Furthermore, emerging evidences by *Temel et al., (2010)* and *Ferrell et al., (2017)* shows that providing palliative care early in the course of advanced cancer improves a variety of important outcomes, including quality of life, symptom load, mood, and health-care utilization.

In summary, as shown in palliative care research for other critical diseases, palliative care may provide further support to the multidisciplinary approach to HCC care, particularly in the area of symptom control. As a result, a greater understanding of the specific needs of patients with HCC is required in order to meet their palliative care needs throughout the course of the disease. Early development of palliative care services to complement the HCC treatment protocol is also expected to dramatically improve patient care.

CONCLUSION

According to the current study findings: It could be concluded that the outcomes of the current research support the current research hypothesis; study group experienced better quality of life than control group, Study group had less symptoms intensity than control

group and Study group had an improved mood than patients in control group. The early palliative care has reached its target group according to the WHO's definition and improves the quality of life, relieves pain and other symptoms either from the disease or from the treatment, improves mood.

RECOMMENDATIONS

According to the results of the current research work, the researchers suggested the upcoming recommendations:

- It is recommended that early palliative care should be initiated early once the patient diagnosed in order to be integrated with medical treatment.
- This research has provided a starting point for further studies regarding health services research in palliative care. Future directions for this research include completing the ongoing care and assessing barriers to palliative care referral as perceived by referring oncologists and developing palliative care research in other populations, and developing measures to adequately assess palliative care interventions.
- Finally, research is needed to determine how indicators for high-quality palliative care for cancer and non-cancer patients may be established in hospitals.

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تأثير تطبيق الرعاية الملطفة المبكرة على نتائج مرضى سرطان الكبد

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الخلاصة

يعتبر سرطان الكبد هو خامس أكثر أنواع السرطانات شيوعاً في العالم وثاني أكبر سبب للوفاة المرتبطة بالسرطان. يواجه مرضى سرطان الكبد مجموعة واسعة من الأعراض الشديدة بما يكفي للتأثير على جودة حياتهم وعلى الوظائف البدنية لهؤلاء المرضى، لذلك يجب على الممرضات تطوير استراتيجيات تعاونية متعددة التخصصات لعلاج هذه الأعراض. تهدف هذه الدراسة إلى تقييم تأثير تطبيق الرعاية الملطفة المبكرة على نتائج مرضى سرطان الكبد. وتم استخدام التصميم شبه التجريبي بهذه الدراسة على عينة مقترحة مكونة من 114 مريضاً بالغاً تتراوح أعمارهم بين 20 و 60 عامًا من كلا الجنسين الذين تم تشخيصهم بسرطان الكبد. تم إجراء البحث في كل من الأقسام الداخلية والعيادة الخارجية لمتابعة المرضى بمستشفى كبد المحلة التعليمي التابعة للهيئة التعليمية للمعاهد والمستشفيات التابعة لوزارة الصحة المصرية. أظهرت النتائج أن هناك تأثيراً جيداً فيما يتعلق بجودة الحياة وشدة الأعراض والحالة النفسية بعد أسبوعين من تنفيذ الرعاية الملطفة المبكرة والمتابعة. وانتهت الدراسة إلى أن الرعاية الملطفة المبكرة تحسن نوعية الحياة وتخفف من حدة الأعراض سواء المصاحبة للمرض أو الآثار الجانبية للعلاج وتحسن أيضاً من الحالة المزاجية والنفسية لدى مرضى سرطان الكبد. وتوصي الدراسة بضرورة بدأ الرعاية الملطفة المبكرة في وقت مبكر بمجرد تشخيص المريض حتى تتكامل مع العلاج الطبي. قدم أيضاً هذا البحث نقطة انطلاق لمزيد من الدراسات المتعلقة ببحوث الخدمات الصحية في الرعاية الملطفة.

الكلمات المرشدة: سرطان الكبد، الرعاية الملطفة، نتائج المرضى