

### Relationship of the quality of life in capecitabine-treated colorectal cancer patients to their sociodemographic characteristics and drugrelated adverse effects

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### Abstract

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**Background:** Colorectal cancer (CRC) is the third most prevalent cancer worldwide with 1.80 million new cases and 862,000 deaths in 2018. Depending on the stage, upfront surgery is the main form of treatment, followed by adjuvant chemotherapy. Many drugs were approved by the U.S. Food and Drug Administration for the treatment of CRC, one of which is Capecitabine. During cancer treatment, patient-reported symptoms and quality of life parameters can provide additional information to evaluate and compare the efficacy and toxicity of the treatments. Despite the importance of this issue, there is no published data that evaluates this vital parameter in Iraqi patients receiving anti-cancer drugs, in general, or those on Capecitabine, in particular. **Objective:** To evaluate the relationship between quality of life in capecitabine-treated colorectal cancer patients and their sociodemographic characteristics as well as drug-related adverse effects.

**Methods:** A cross-sectional, open-label study was conducted at Al-Amal and Oncology Teaching Hospitals in Baghdad during the period from November 2021 to June 2022. A convenient sampling method was adopted to enrol patients in the current study. Quality of life assessment was performed using the European Organization for Research and Treatment of Cancer quality of life questionnaire (QLQ-C30). Microsoft Excel 2019 and the Statistical Package for the Social Sciences (SPSS, Version 25) were used for data entry and analysis. The descriptive analysis focused on frequencies and percentages. Continuous variables were presented as (mean  $\pm$  Standard Deviation). Categorical data were presented as proportions and the Chi-squared test was used to study the associations between variables. The level of significance was considered at P $\leq$ 0.05. **Results:** A total of 102 patients were enrolled in the current study. Generalized fatigue was the most common adverse event (63.7%) of participants. Only 6.9% of participants had abnormal renal function tests. Some capecitabine-treated patients had good quality of life, others did not.

**Conclusion:** The quality of life of capecitabine-treated colorectal cancer patients seems to be sensitive to their sociodemographic characteristics and adverse effects of the drug.

Keywords: Adverse effects, Capecitabine, Colorectal cancer, Quality of life, Sociodemographic.

### Introduction:

Colorectal cancer (CRC) is the third most prevalent cancer worldwide (1,2,3). From a clinical point of view, CRC is usually subdivided as proximal or rightsided when they originate from colon sections proximal to the splenic flexure (cecum, ascending colon and transverse colon), whereas distal or left-sided colon tumors arise distally to descending colon or sigmoid colon, and classified as

\* MSc student at Department of Pharmacology/ College of Medicine/ University of Baghdad, Iraq. <u>Shelan.Amer1206b@comed.uobaghdad.edu.iq</u> \*\* Department of Medicine/ College of Medicine/ University of Baghdad. <u>Mazin.j@comed.uobaghdad.edu.iq</u> \*\* Department of Pharmacology/ College of Medicine/ University of Baghdad,. <u>mohammed.a@comed.uobaghdad.edu.iq</u> rectal cancers when they arise within 15cm of the anal sphincter (4). The simplest method of CRC recognition, along with the case history, is per rectum examination. During this examination, 70% of rectal cancers and 30% of colon cancers are recognized. The accuracy of the examination increases with the experience of the surgeon (5). Depending on the stage, upfront surgery is the main form of treatment, followed by adjuvant chemotherapy (6). Many drugs were approved by the U.S. Food and Drug Administration (FDA) to treat CRC including Capecitabine, Fluorouracil (5-FU), Irinotecan, Oxaliplatin and Trifluridine/tipiracil. Capecitabine, an oral prodrug of 5-Fluorouracil (5-FU), is a chemotherapeutic agent that was approved in 2001 and has been shown to be effective in the treatment of CRC, gastric cancer, and breast cancer (7, 8). The

mechanism of action of the drug is presented in Figure 1.



**Figure 1. Mechanism of action of Capecitabine (9)** *CE, carboxyl esterase; CD, cytidine deaminase; TP, thymidine phosphorylase; 5'-DFCR, 5'-deoxy-5fluorocytidine; 5'-DFUR, 5'-deoxy-5-fluorouridine; DHFU, dihydro-5-fluorouracil; 5FU, fluorouracil; DPD, dihydropyrimidine dehydrogenase.* 

During cancer treatment, monotoring patient-reported symptoms and Quality of Life (QoL) can provide additional information to evaluate and compare the efficacy and toxicity profiles of the treatments. Furthermore, the incorporation of patient-reported outcomes into toxicity reporting in clinical trials has been recommended to overcome the potential underreporting of the severity of subjective adverse events by physicians in clinical trials (10). There is a little debate about the importance of QoL in patients with advanced CRC, yet QoL data are not standardized and rarely emphasized in clinical trial reporting compared to overall survival, progression-free survival and objective response rate (11). Despite being a recognized component endpoint by the United States FDA, it was noted that OoL is frequently inadequately captured in CRC clinical trials and is rarely translated into clinical decision-making (12). Despite the importance of patients' QoL while they are on anticancer treatment, there was no published data in the literature evaluating this vital parameter in Iraqi patients receiving anti-cancer drugs, in general, or those on Capecitabine, in particular. The current study aimed to evaluate the relationship between quality of life in capecitabine-treated colorectal cancer patients and their sociodemographic characteristics as well as drugrelated adverse effects.

### Methods

This is a cross-sectional, open-label study conducted at Al-Amal and Oncology Teaching Hospitals in Baghdad from November 2021 to June 2022. Patients were asked to participate voluntarily after an adequate explanation about the aim and method of the study. All participants were assured of anonymity and confidentiality of the information. Verbal consent was obtained from each participant. A convenient sampling method was adopted to enroll the participants in the current study. It was planned to recruit 50-100 patients who were diagnosed with CRC and were on capecitabine treatment for at least one month. Their age should be  $\geq 18$  years and they should be able to provide an informed consent. Patients with other types of cancer, with chronic diseases (respiratory, renal and/ or hepatic, diabetes mellitus, hypertension, cerebrovascular and/ or cardiovascular disease), pregnant and/ or nursing mothers were excluded from the study. Patients with CRC treated with radiotherapy, were also excluded. The data was collected using a validated questionnaire through interviews performed by the researchers with the participants, and included: Sociodemographic characteristics (gender, age, education, residence, and employment), adverse events associated with capecitabine treatment (liver function test, renal function test, and white blood cell count) and assessment of QoL of patients. The latter was done using the European Organization for Research and Treatment of Cancer (EORTC) QoL questionnaire (QLQ-C30; (13) which had been developed as a quantitative measure of health-related OoL for use in clinical trials of cancer patients. The 30 items of the EORTC QLQ-C30 cover 15 domains (Table 2.2; (14). Scoring and the interpretation of scores for the EORTC QLQ-C30 were performed according guidelines provided ((14, 15). Microsoft Excel 2019 and the Statistical Package for the Social Sciences (SPSS, Version 25) were used for data entry and analysis. The descriptive analysis focused on frequencies and percentages. Continuous variables were presented as (mean  $\pm$  Standard Deviation).. The ANOVA and t-tests were used todetect the differences between means. The level of significance was considered at  $P \le 0.05$ .

 Table 2.1: Scoring the QLQ-C30 version 3.0 (14)

Scale/ item	Number of items	Items range value	Items number
Global health status/QoL	2	6	29, 30
Functional scales			
Physical functioning	5	3	1 to 5
Role functioning	2	3	6,7
Emotional functioning	4	3	21 to 24
Cognitive functioning	2	3	20, 25
Social functioning	2	3	26, 27
Symptom scales/items			
Fatigue	3	3	10, 12, 18
Nausea and vomiting	2	3	14, 15
Pain	2	3	9, 19
Dysnea	1	3	8
Insomnia	1	3	11
Appetite loss	1	3	13
Constipation	1	3	16
Diarrhea	1	3	17
Financial difficulties	1	3	28

#### Results

Demographic data: A total of 102 patients were enrolled in current study (52% males and 48% females). Patients between 51-60 years of age constituted the largest group (30.4%), 88.2% were from urban areas, 5.5% were unemployed and 37.3% had college or higher education (Table 3.1).

Table 3.1: Demographic	characteristics of
participants	

Demographic characteristic		No.	%
Gender	Gender Male		52.0
	Female	49	48.0
Age group (year)	<40	9	8.8
	41-50	18	17.6
	51-60	31	30.4
	61-70	25	24.5
	>70	19	18.6
Education	Primary school	31	30.4
	Secondary school	33	32.4
	College or higher	38	37.3
Residency	Urban	90	88.2
	Rural	12	11.8
Employment	Unemployed	77	75.5
	Employed	25	24.5

**Quality of Life of participants on Capecitabine treatment:** Regarding the functional scales of EORTC QLQ-C30, emotional and social functioning were the most affected, with a lower mean than other scales. Among the symptoms scale, fatigue and appetite loss were the most affected, with a higher mean than other scales (Table 3.2).

# Table 3.2: The mean±SD scores of EORTC QLQ-C30 domains among participants

EORTC QLQ-C30 domain	Mean score±standard deviation
Global health status/QoL	57.1±25.07
Functional scales	
Physical functioning	73.9±22.46
Role functioning	81.9±23.69

e effects.		
Emotional functioning	70.8±22.02	
Cognitive functioning	82.0±21.06	
Social functioning	71.7±24.90	
Symptom scales		
Fatigue	38.9±27.65	
Nausea and vomiting	18.3±20.38	
Pain	22.5±23.29	
Dyspnea	14.7±22.28	
Insomnia	19.6±23.14	
Appetite loss	32.4±24.57	
Constipation	18.6±24.63	
Diarrhea	21.6±26.38	
Financial difficulties	44.1±28.20	
QLQ-C30 summary score	43.6±4.9	

Participants' demographic data and their quality of life: There was a significant difference between the means of Global health status/QoL, physical functioning, role functioning, social functioning and fatigue for the different age groups (P<0.05; Table 3.3). As for gender, there were significant differences in the mean Global health status/QoL, physical functioning, role functioning, cognitive functioning, social functioning and fatigue between males and females (P<0.05; Table 3.4). There was a significant difference between the mean Global health status/QoL, physical functioning, role functioning, social functioning, fatigue, diarrhea, and financial difficulties for urban and rural residence (P<0.05; Table 3.5). There was a significant difference between the mean Global health status/QoL, physical functioning, role functioning, emotional functioning, social functioning, fatigue, nausea and vomiting, pain, dyspnea, and financial difficulties based on employment status (P<0.05; Table 3.6). There was a significant difference between the mean Global health status/QoL, physical functioning, role functioning, emotional functioning, social functioning, fatigue, nausea and vomiting, pain, and financial difficulties for different educational levels (P<0.05: Table 3.7).

Table 3.3: Mean±SD QoL, functional scales and symptom scales for participants' age groups

EORTC QLQ-C30 domain	Age groups (year)					
(Mean±SD)	≤40	41-50	51-60	61-70	>70	P-value
Global health status/QoL	70.3±20.8	68.0±22.9	$58.8 \pm 24.6$	51.0±23.6	45.6±26.1	0.018*
Functional scales						
Physical	88.9±14.9	$85.9 \pm 9.6$	73.5±21.6	74.4±17.3	55.0±28.7	< 0.001*
Role	90.7±18.8	95.3 ±9.5	82.7±23.3	$78.0{\pm}20.5$	68.4±31.8	0.006*
Emotional	83.3±15.5	74.5±26.7	65.3±24.5	68.3±18.3	73.6±18.0	0.200
Cognitive	81.4±22.7	93.5±12.9	80.1±18.9	82.6±23.3	73.6±23.7	0.068
Social	85.1±17.5	$84.2 \pm 18.4$	73.6±21.4	67.3±29.0	56.1±24.3	0.002*
Symptom scales						
Fatigue	$17.2\pm22.9$	24.6±17.2	38.3±25.1	42.6±26.9	$58.4 \pm 29.8$	< 0.001*
Nausea and vomiting	12.9±23.2	$13.8 \pm 14.2$	16.6±17.7	22.6±23.0	21.9±24.2	0.499
Pain	$9.2 \pm 16.8$	$11.1 \pm 14.0$	23.6±24.6	27.3±23.9	31.5±24.7	0.021*
Dyspnea	11.1±23.5	9.2 ±15.3	18.2±25.5	14.6±21.6	15.7±23.2	0.716
Insomnia	$7.4 \pm 14.6$	$12.4\pm20.2$	$22.5\pm26.3$	$20.0\pm23.5$	26.3±21.0	0.192
Appetite loss	$25.9\pm22.2$	20.3±23.2	31.1±20.9	$40.0{\pm}25.4$	38.5±27.8	0.068
Constipation	11.1±16.6	16.6±28.5	$15.0{\pm}20.7$	20.0±21.5	28.0±31.9	0.350
Diarrhea	$18.5 \pm 24.2$	16.6±23.5	26.8±30.3	18.6±21.6	22.8±29.5	0.681
Financial difficulties	$29.6 \pm 26.0$	33.3±25.5	$44.0\pm29.0$	48.0±30.5	56.1±22.3	0.059
QLQ-C30 summary score	41.7 ±6.1	43.0 ±4.1	43.6 ±4.6	$44.3 \pm 5.2$	$43.8 \pm 5.4$	0.721

ANOVA test. \*: Statistically significant at P<0.05. SD: Standard deviation.

symptom scales	o tor partic	ipants ge	nuei
EORTC QLQ-		Gender	
C30 domain Mean ± SD	Male	Female	P-value
Global health status/QoL	49.6±25.0	65.1±22.7	0.002*
Functional scales			
Physical functioning	69.1±24.5	78.9±18.9	0.028*
Role functioning	74.8±27.4	89.4±15.8	0.002*
Emotional functioning	67.4±23.8	74.4±19.4	0.107
Cognitive functioning	77.0±22.9	87.4±17.5	0.012*
Social functioning	66.3±26.5	77.8±21.6	0.016*
Symptom scales / i	items		
Fatigue	45.9±29.3	31.2±23.7	0.007*
Nausea and vomiting	19.4±21.6	17.0±19.0	0.540
Pain	26.4±26.6	18.3±18.3	0.081
Dyspnea	15.0±24.0	$14.2\pm20.4$	0.856
Insomnia	$22.6 \pm 25.9$	16.3±19.3	0.170
Appetite loss	35.2±25.6	29.2±23.2	0.222
Constipation	22.0±26.9	$14.9 \pm 21.5$	0.150
Diarrhea	23.2±27.4	19.7±25.3	0.501
Financial difficulties	48.2±29.6	39.4±26.0	0.109
QLQ-C30 summary score -test. *: Statistically	43.4±5.4	43.7±4.4	0.711

Table 3.4: Mean±	SD QoL,	functional	scales	and
symptom scales for	participa	nts' gender		

t-test. \*: Statistically significant at P<0.05. SD: Standard deviation.

Table 3.5: Mean±SD QoL, functional scales and symptom scales for participants' place of residence

EORTC QLQ-C30	purticipu	Residence	
domains Mean SD	Urban	Rural	P-value
Global health status/QoL	59.1±24.4	41.6±25.1	0.022*
Functional scales			
Physical functioning	76.6±21.3	52.7±20.1	< 0.001*
Role functioning	83.7±23.3	$68.0 \pm 22.9$	0.031*
Emotional functioning	71.5±21.9	65.2±22.4	0.355
Cognitive functioning	82.7±20.6	76.3±24.0	0.326
Social functioning	73.3±24.9	56.9±19.4	0.028*
Symptom scales / items	3		
Fatigue	36.4±27.5	57.4±21.0	0.013*
Nausea and vomiting	18.1±20.0	19.4±23.3	0.837
Pain	21.2±22.9	31.9±25.0	0.138
Dyspnea	$14.8\pm22.4$	13.8±22.2	0.893
Insomnia	19.2±22.3	22.2±29.5	0.679
Appetite loss	31.8±24.9	36.1±22.2	0.575
Constipation	$17.0{\pm}24.0$	$30.5 \pm 26.4$	0.074
Diarrhea	19.6±24.4	36.1±36.1	0.042
Financial difficulties	41.1±27.3	66.6±24.6	0.005
QLQ-C30 summary score	43.6±4.8	43.6±6.2	0.990

t-test. \*: Statistically significant at P<0.05. SD: Standard deviation.

Table	3.6:	Mean±S	D Qol	, fun	ctional	scales	and
sympt	om so	cales for p	oarticij	oants'	employ	ment st	atus

symptom scales for	participants	employmen	t status
EORTC QLQ-C30		Employment	
domains Mean±SD	Unemployed	Employed	P-value
Global health status/QoL	51.5±24.4	74.3±18.4	<0.001*
Functional scales			
Physical functioning	69.3±23.5	87.7±10.3	< 0.001*
Role functioning	77.4±24.8	95.3±12.2	0.001*
Emotional functioning	66.9±22.3	82.6±16.3	0.002*
Cognitive functioning	79.8±21.3	88.6±19.0	0.069
Social functioning	67.5±26.0	84.6±15.1	0.002*
Symptom scales / items			
Fatigue	43.1±29.2	25.7±16.2	0.006*
Nausea and vomiting	19.6±21.0	$14.0{\pm}17.7$	0.226
Pain	27.7±23.8	6.6±11.7	< 0.001*
Dyspnea	17.3±23.3	6.6±16.6	0.037*
Insomnia	21.6±24.0	13.3±19.2	0.119
Appetite loss	35.0±25.3	$24.0\pm20.4$	0.050
Constipation	19.4±24.9	16.0±23.8	0.542
Diarrhea	22.0±26.8	20.0±25.4	0.734
Financial difficulties	48.4±29.3	30.6±19.0	0.005*
QLQ-C30 summary score	43.6±5.0	43.5±4.6	0.901

*t-test.* \*: Statistically significant at P<0.05. SD: Standard deviation.

Table 3.7: Mean±SD QoL, functional scales and symptom scales for participants' educational levels

EORTC	Educational level			
QLQ-C30 domains Mean±SD	Primary school	Secondary school	College or higher	P-value
Global health status/QoL	45.4±24.5	54.0±23.9	69.2±21.4	<0.001*
Functional scal	les			
Physical functioning	60.2±24.2	72.5±22.4	86.1±12.3	<0.001*
Role functioning	70.9±25.0	79.2±26.0	92.9±14.3	<0.001*
Emotional functioning	66.1±19.3	65.4±23.6	79.3±21.0	0.009*
Cognitive functioning	77.4±22.5	80.3±18.8	87.2±21.0	0.131
Social functioning	58.6±25.4	73.7±25.3	80.7±19.5	0.001*
Symptom scale	es / items			
Fatigue	54.1±25.6	36.3±30.3	28.6±21.2	< 0.001*
Nausea and vomiting	25.8±25.0	15.6±18.1	14.4±16.5	0.046*
Pain	32.7±22.9	22.7±24.5	14.0±19.1	0.003*
Dyspnea	18.2±22.5	17.1±25.1	9.6±18.8	0.208
Insomnia	21.5±20.2	23.2±28.2	$14.9\pm20.0$	0.278
Appetite loss	36.5±21.6	33.3±26.3	$28.0\pm25.1$	0.351
Constipation	$23.6 \pm 28.7$	21.2±21.7	12.2±22.4	0.124
Diarrhea	$27.9 \pm 25.9$	22.2±29.6	15.7±22.9	0.161
Financial difficulties	61.2±24.4	39.3±28.2	34.2±25.0	<0.001*
QLQ-C30 summary score	44.1±4.7	43.3±5.0	43.4±5.1	0.765
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ANOVA test. \*: Statistically significant at P<0.05. SD: Standard deviation.

## *Relationship of the quality of life in capecitabine-treated colorectal cancer patients to sociodemographic characteristics and drug-related adverse effects.*

**Participants' quality of life and their adherence to capecitabine treatment:** The current study showed a significant difference between the mean Global health status/QoL, physical functioning, role functioning, emotional functioning, social functioning, fatigue, nausea and vomiting, pain, dyspnea, insomnia, and financial difficulties and the leval of adherence to to capecitabine treatment (Table 3.8).

# Table 3.8: Mean±SD QoL, functional scales and symptom scales for participants' level of adherence to capecitabine treatment

to capecitabi	ine treatm	ent			
EORTC	Adherence				
QLQ-C30	Low	Medium	High	P-value	
domains			0		
Mean±SD					
Global	$47.9 \pm 26.4$	$68.8 \pm 23.2$	$47.5 \pm 8.7$	< 0.001*	
health					
status/QoL					
Functional scal	les				
Physical	63.8±26.5	79.8±16.7	81.5±16.5	0.001*	
functioning					
Role	$72.0\pm27.5$	88.1±19.6	88.2±15.3	0.003*	
functioning					
Emotional	$62.5 \pm 22.5$	75.3±20.9	78.4±17.9	0.007*	
functioning		05.0.10.5	0.5.0.1.6.1	0.000.1	
Cognitive	74.1±23.2	87.0±18.7	87.2±16.1	0.009*	
functioning	(0.0.0(0)	75 0 22 0	00.0.14.1	0.001	
Social	60.0±26.3	75.9±22.0	88.2±14.1	< 0.001	
functioning Symptom scale	s / items				
• •					
Fatigue	$50.0\pm 28.3$	30.8±23.4	33.9±28.9	0.004*	
Nausea and vomiting	24.7±3.9	14.7±2.2	16.4±3.9	0.005*	
Pain	26.0±4.1	17.2±2.5	20.3±4.9	< 0.001*	
Dyspnea	20.8±23.4	14.0±23.0	1.9±8.0	0.012*	
Insomnia	24.1±25.0	20.0±22.9	7.8±14.5	0.049*	
Appetite loss	39.1±24.9	$28.8\pm24.2$	25.4±22.1	0.070	
Constipation	21.6±25.6	22.0±3.2	29.0±7.0	0.517	
Diarrhea	20.0±27.0	24.4±26.0	17.6±26.6	0.596	
Financial difficulties	57.5±26.1	39.2±24.9	25.4±27.7	<0.001*	
QLQ-C30 summary score	43.7±5.0	43.9±5.2	42.5±4.9	0.610	

ANOVA test. \*: Statistically significant at P<0.05. SD: Standard deviation.

**Participants' quality of life and their experience of capecitabine-related adverse effects:** The QLQ-C30 summary score means were significantly higher among patients who experienced capecitabine-related adverse events except for hand / foot, abnormal renal function, and abnormal liver function (Table 3.9).

Table 3.9: Mean±SD QoL, functional scales and symptom scales for participants' development of adverse effects

Adverse effect	t	QLQ-C30	P-value
		summary score -	
		Mean±SD	
Weakness	Yes	44.8±4.9	< 0.001*

	No	41.3±4.1	
Nausea	Yes	45.0±4.7	0.002*
	No	42.0±4.7	_
Diarrhea	Yes	45.2±4.6	0.010*
	No	42.6±4.9	
Anaemia	Yes	45.3±5.0	0.013*
	No	42.7±4.7	
Hand / foot	Yes	43.2±4.9	0.173
	No	43.2±4.9	_
Low white	Abnormal	45.4±4.6	0.047*
blood cells count	Normal	43.0±4.9	
Vomiting	Yes	45.6±4.8	0.049*
	No	43.1±4.8	_
Abnormal	Abnormal	43.9±4.9	0.837
liver function	Normal	43.9±5.9	
Abnormal	Low	44.4±6.2	0.637
renal function	Normal	43.5±4.8	

### **Discussion:**

Demographic data of participants

Results of current study revealed that 102 patients with colorectal cancer (CRC) on capecitabine treatment were enrolled in current study and 52% of them were males. The age of participants was more than 50 years. Similar results were obtained by another study which showed that the number of males, aged >70 years and affected with CRC, was higher than females (16). Siegel et al. (2017) reported that most of the participants in their study were males >50 years of age, which somewhat coincides with the current study. Another study had revealed that 89% of the CRC cases in that study were diagnosed at an age of  $\geq$ 50 years (17). The molecular and pathophysiologic changes that occur throughout life, which progressively modify molecular homeostasis of colonic epithelial cells leading to neoplasia, might explain the linkage between CRC incidence and age (18). Quality of Life of participants on Capecitabine treatment. When comparing the QoL of patients from the current study with those from another study (19) depending on the EORTC QLQ-C30, a better QoL was detected in the current study regarding all domains of the EORTC QLQ-C30 (except for nausea, appetite loss, constipation, diarrhea and financial problem). Better QoL (including all domains of the EORTC QLQ-C30 ) was detected in other studies done in Taiwan (20) and Slovenia (21) than the current study. The factors that might have influenced the QoL of our cases will be explored in the subsequent sections. Participants' quality of life and their demographic data The current study showed that younger age patients had better QoL (regarding physical functioning, role functioning, social functioning, fatigue, and pain) than older ones. In agreement with these findings, Breadner et al. (2018) reported that dose reduction of Capecitabine had improved QoL in older or frail patients with CRC. Another study that was done by Ward et al. (2014) revealed that there was significant heterogeneity in functional measurements and QoL among elderly patients with metastatic CRC on Capecitabine treatment. Males had a significantly better QoL (regarding physical functioning, role functioning, cognitive functioning, and social functioning) than females. However, a significantly better QoL was reported by females (regarding the fatigue domain). A study feom Brazil revealed that females had statistically significant improvements in six QLQ-C30 domains (emotional function, nausea/vomiting, pain. constipation, financial problems, and body image), while men had statistically significant improvements in eight QLQ-C30 domains (emotional function, social function, pain, insomnia, appetite loss, constipation, financial problems, and future perspective) (22). The current study showed that urban-living patients had a significantly better OoL in most of the OLO-C30 domains. Patients with college or higher educations had a significantly better QoL regarding Global health status/QoL, most of the functional status, fatigue, nausea and vomiting, pain, as well as financial difficulties. These results might be attributed to the good knowledge about the disease and its management which resulted in better compliance and avoiding aggravating factors. Those living in urban areas usually experience comfortable social life that would positively affect their compliance to treatment. However, to our knowledge, there were no other studies that discussed the association between residency and education with QoL in CRC patients on Capecitabine treatment. Participants' QoL and their experience of capecitabinerelated adverse effects. In the current study, according to the EORTC QLQ-C30, symptom scales/items have shown low scores. In addition, the adverse events (except hand-foot syndrome, abnormal liver function test and abnormal renal function test) have shown better QoL as determined by the QLQ-C30 summary score. In agreement with these results, a study from Germany revealed that the hand-foot syndrome associated with Capecitabine use had no negative impact on the QoL (23). In contrast, another study reported that the adverse events of chemotherapy affected a greater number of QoL indicators and concluded that it would be necessary to make health professionals aware of the importance of chemotherapy-associated adverse reactions (24). Indeed, the adverse events of chemotherapy negatively impact the QoL, but the controversy might be related to the severity of the adverse events, the clinical state of the patient and/ or other impacting factors. Participants' QoL and their adherence to capecitabine treatment The current study revealed that high adherence to the treatment had a significant relationship with better QoL (regarding physical functioning, role functioning, emotional functioning, cognitive functioning, social functioning, and dyspnea) while patients with medium adherence had a significantly better QoL (regarding fatigue, nausea and vomiting, and pain). A previous study had concluded that a higher adherence score was significantly associated with better health-related QoL dimensions such as physical functioning and less

fatigue (25), while another study revealed a statistically non-significant correlation between adherence and the functional and symptom scales of the questionnaire before and after chemotherapy, with the exception of dyspnea (26). Good adherence to capecitabine treatment in patients with CRC results in improvement in symptoms which would be positively reflected on patients' QoL.

### Ethical Clearance:

Ethical Approval was obtained from the Scientific Research Ethics Committee and Department of Pharmacology/ College of Medicine, University of Baghdad.

### Conclusion:

The quality of life of patients with colorectal cancer on capecitabine-treatment seems to be sensitive to patients' sociodemographic characteristics as well as to capecitabine-related adverse effects.

Author's Contributions: All authors equally contributed to the study.

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## العلاقة بين نوعية وجودة الحياة لمرضى سرطان القولون الذين يخضعون للعلاج بالكابسيتابين في المستشفيات العراقية مع خصائصهم الديمو غرافية الاجتماعية والتاثيرات الجانبية للدواء

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### الخلاصة:

الخلفية: يعتبر سرطان القولون والمستقيم ثالث أكثر أنواع السرطانات انتشارًا في جميع أنحاء العالم ، حيث تم تشخيص 1.80 مليون حالة جديدة من السرطان وتوفي 862 ألف مريض في عام 2018. اعتمادًا على المرحلة ، تعد الجراحة الأولية هي الشكل الرئيسي للعلاج ، يليها العلاج الكيميائي المساعد. علاوة على ذلك ، تمت الموافقة على العديد من الأدوية من قبل إدارة الغذاء والدواء الأمريكية لعلاج سرطان القولون والمستقيم بما في ذلك Capecitabine ومع ذلك ، أثناء علاج السرطان ، يمكن أن يوفر قياس تجربة الأعراض التي أبلغ عنها المريض ونوعية الحياة معلومات إضافية لتقييم ومقارنة الفعالية والسمية للعلاجات. على الرغم من أهمية نوعية حياة المرضى أثناء تلقيهم العلاج المريض ونوعية الحياة معلومات إضافية لتقييم ومقارنة الفعالية والسمية للعلاجات. على الرغم من أهمية نوعية حياة المرضى أثناء تلقيهم العلاج المصاد للسرطان ، لم تكن هناك بيانات منشورة في الأدبيات التي تقيم هذا المعيار الحيوي فيما يتعلق بالمرضى العراقيين الذين يتلقون الأدوية المصادة للسرطان بشكل عام ، أو أولئك الذين يتناولون خاص. لذلك ، كان الهدف من الدراسة الحالية هو تقيم العلاقة بين نوعية وجودة الحيات الذين يتلقون الأدوية المصادة للسرطان بعلاج بالمين الذين يتناولون خاص. لذلك ، كان الهدف من الدراسة الحلام وي قيما يتعلق بالمرضى العراقيين الذين يتلقون الأدوية المضادة للسرطان بشكل عام ، أو أولئك الذين يتناولون خاص. لذلك ، كان الهدف من الدراسة الحالية هو تقيم العلاقة بين نوعية وجودة الحياة لمرضى سرطان القولون العلاج بالكابسيتابين في المستشيات

الطريقة: تم إجراء دراسة مقطعية مفتوحة التسمية في مستشفيات الأمل والأورام التعليمية في بغداد خلال الفترة من تشرين الثاني (نوفمبر) 2021 إلى حزيران (يونيو) 2022. تم اعتماد طريقة أخذ عينات مناسبة لتسجيل المرضى في الدراسة الحالية. تم إجراء تقييم جودة الحياة باستخدام استبيان المنظمة الأوروبية لأبحاث وعلاج السرطان حول جودة الحياة مناسبة لتسجيل المرضى في الدراسة الحالية. تم إجراء تقييم جودة الحياة باستخدام استبيان المنظمة الأوروبية لأبحاث وعلاج السرطان حول جودة الحياة مناسبة لتسجيل المرضى في الدراسة الحالية. تم إجراء تقييم جودة الحياة باستخدام استبيان المنظمة الأوروبية لأبحاث وعلاج السرطان حول جودة الحياة (QLQ-C30). تم استخدام(2019 Microsoft Excel) والحزمة الإحصائية للعلوم الاجتماعية الأوروبية لأبحاث وعلاج السرطان حول جودة الحياة (QLQ-C30). تم استخدام(2019 Microsoft Excel) والحزمة الإحصائية للعلوم الاجتماعية لإدخال البيانات وتحليلها (SPS الإصدار 25). ركز التحليل الوصفي على التكرارات والنسب المئوية. تم عرض المتغيرات المستمرة على أنها متوسط (ل البيانات وتحليلها (SPS) الإصدار 20). ركز التحليل الوصفي على التكرارات والنسب المئوية. تم عرض المتغيرات المستمرة على أنها متوسط (ل الابتات وتحليلية المتغيرات). وله مستوى الأهمية عند20.02 التحليل الوصفي على التكرارات والنسب المئوية. تم عرض المتغيرات المستمرة على أنها متوسط (ل الابتات وتحليلية).

النتائج: تم تسجيل ما مجموعه 102 مريضا في الدراسة الحالية. كان التعب العام هو الحدث الضار الأكثر شيوعًا حيث ظهر في 63.7 ٪ من المشاركين. أيضًا ، كان 6.9 ٪ فقط من المشاركين لديهم اختبارات وظائف الكلى غير الطبيعية. بالإضافة إلى ذلك ، كان بعض المرضى الذين عولجوا بواسطة يتمتعون بنوعية حياة جيدة ، والبعض الآخر لم يكن كذلك.

الاستنتاج: يبدو أن نوعية حياة مرضى سرطان القولون والمستقيم المعالجين بواسطة دواء بالكابسيتابين حساسة لخصائصهم الديموغرافية الاجتماعية والتأثيرات السلبية للدواء..

الكلمات المفتاحية: الاعراض الجانبية, كاباستابين, سرطان القولون والمستقيم, جودة الحياة, الخصائص الاجتماعية الديموغر افية.