# **Quality of life evaluation in cancer patients to submitted to chemotherapy**

AVALIAÇÃO DA QUALIDADE DE VIDA DE PACIENTES COM CÂNCER SUBMETIDOS À QUIMIOTERAPIA

EVALUACIÓN DE LA CALIDAD DE VIDA DE PACIENTES CON CÁNCER SOMETIDOS A QUIMIOTERAPIA

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#### **ABSTRACT**

This descriptive and cross-sectional study aimed to assess the Quality of Life (QoL) of cancer patients who were receiving chemotherapy. The instrument European Organization for Research and Treatment of Cancer - Quality of Life Questionnaire Core-30 (EORTC QLQ-C30) was used for data collection. The sample consisted of 30 patients who signed the informed consent term. Data were analyzed in SPSS software. The QLQ-C30 showed that, for physical, cognitive and social functions, and role performance mean scores ranged from 71.26 to 75.12, demonstrating a satisfactory level. In the emotional function, the mean score was low (55.46). On the symptoms scales, there were a predominance of insomnia, with a mean score of 34.44, followed by pain 23.33 and fatigue 22.31. The QoL was satisfactory in all domains except for the emotional function, which scored low demonstrating that the collateral effects of chemotherapy exert a negative influence on patients' quality of life.

# **KEY WORDS**

Neoplasms.
Drug therapy.
Quality of life.
Nursing care.
Oncologic nursing.

#### **RESUMO**

Estudo descritivo e transversal, desenvolvido com o objetivo de avaliar a Qualidade de Vida (QV) de pacientes com câncer, submetidos à quimioterapia. Para a coleta de dados, utilizou-se o instrumento European Organization for Research and Treatment of Cancer – Quality of Life Questionnaire Core-30 (EORTC QLQ-C30). A amostra constitui-se de 30 pacientes que assinaram o consentimento informado. Os dados foram analisados pelo software SPSS. O QLQ-C30 mostrou que a pontuação média das funções física, cognitiva e social, e desempenho de papel, variou de 71,26 a 75,12, demonstrando um nível satisfatório. Na função emocional, a média foi baixa, de 55,46. Nas escalas de sintomas, houve o predomínio da insônia com uma média de 34,44, seguida de dor (23,33) e fadiga (22,31). A QV foi satisfatória em todos os domínios, exceto a função emocional, que foi baixa, demonstrando que os efeitos colaterais da quimioterapia influenciam negativamente a QV dos pacientes.

# **DESCRITORES**

Neoplasias.
Quimioterapia.
Qualidade de vida.
Cuidados de enfermagem.
Enfermagem oncológica.

## **RESUMEN**

Estudio descriptivo y transversal desarrollado con el objetivo de evaluar la Calidad de Vida (CV) de pacientes con cáncer sometidos a quimioterapia. Para la recolección de datos, se utilizó el instrumento European Organization for Research and Treatment of Cancer - Quality of Life Questionnaire Core-30 (EORTC QLQ-C30). La muestra se constituyó de 30 pacientes que firmaron el consentimiento informado. Los datos fueron analizados con el software SPS. El QLQ-C30 mostró que la puntuación promedio de las funciones físicas, cognitiva y social y desempeño de papel varió de 71,26 a 75,12, demostrando un nivel satisfactorio. En la función emocional, el promedio fue bajo de 55,46. En las escalas de síntomas hubo el predominio del insomnio con un promedio de 34,44, seguida de dolor 23,33 y fatiga 22,31. La CV fue satisfactoria en todos los dominios excepto la función emocional que fue baja demostrando que los efectos colaterales de la quimioterapia influyen negativamente la CV de los pacientes.

## **DESCRIPTORES**

Neoplasias. Quimioterapia. Calidad de vida. Atención de enfermería. Enfermería oncológica.

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## INTRODUCTION

Cancer has become a worldwide public health issue, as its prevalence has increased among non-transmissible chronic diseases. Therefore, there is a need for large financial investments, which causes both institutional and social burdens<sup>(1)</sup>.

In Brazil, there were an estimated 466,730 new cancer cases in 2008 and 2009. The most prevalent types of cancer, apart from non-melanoma skin cancer, are prostate and lung cancer among men, and breast and cervical cancer among women. This profile is the same for the world in general<sup>(1)</sup>.

The primary types of cancer treatment include surgery, chemotherapy, radiotherapy, and biotherapy. Surgery is usually the initial treatment of choice for several types of cancer<sup>(2)</sup>. Advancements in surgical techniques, and an improved understanding of the evolution and intensive postoperative care have made it possible to remove tumors from almost any part of the body.

Chemotherapy is one of the most chosen modalities to achieve cure, control and relief It involves the use of cytotoxic substances usually administered systemically (intravenous), and is classified according to its purpose, such as: adjuvant chemotherapy, neoadjuvant chemotherapy, primary chemotherapy, palliative chemotherapy, monochemotherapy, and Quality of Life (QOL) is polychemotherapy<sup>(2)</sup>.

The chemotherapy drug is usually well tolerated by the patients with moderate side effects that are managed by using appropriate doses and taking care when using other drugs, such as antiemetics. The main toxicities are

suppression of the bone marrow, immunosupression, nausea and vomiting, alopecia, renal toxicity, heart toxicity, pulmonary toxicity, neurotoxicity, gonadal lesions, and sterility<sup>(3)</sup>.

The clinical consequences of chemotherapy include: the induction of nausea and vomiting, esophagus lesions, fractures, malnutrition, as well as water-electrolyte and acidbase imbalance, which often lead to the patients refusing to continue with the chemotherapy cycles, thus reducing their health-related quality of life (HRQoL) and compromising treatment effectiveness(4).

Quality of Life (QOL) is often measured to evaluate clinical trials with chemotherapy, to measure side effects. QOL measurement is the best method to evaluate the patient's tolerance to treatment. Chemotherapy should be evaluated considering two important aspects: the toxic effects on tumor cells, as well as the positive and negative impacts on patient quality of life.

QOL measurement in oncology started in the 1940s, with a scale to evaluate the patient's physical function and condition of performance<sup>(5)</sup>.

Now, QOL measurements are fundamental in evaluating cancer treatment outcomes. The quality of life term is seen

as a multidimensional (physical, psychological, social, and spiritual), subjective, dynamic, and bipolar concept<sup>(6)</sup>.

## **OBJECTIVES**

From this perspective, the present study aimed to measure the QOL of patients with cancer treated with antineoplastic chemotherapy.

Specific objectives included:

- Characterizing patients in chemotherapy via sociodemographic and clinical data (gender, age, marital status, education level, religion, diagnosis, and performed treatment);
- Identifying QOL domains affected in cancer patients on chemotherapy; and
- Associating sociodemographic and clinical data with QOL of patients with cancer on chemotherapy treatment.

### **METHOD**

often measured to

with chemotherapy, to

measure side effects.

This is a descriptive, cross-sectional study performed at the Specialized Oncology Center (CEON) in the city of Ribeirão Preto. It is a hospital that sees patients in the Brazilian public health system (the unified health system – SUS), as well as those using health insurance or paying for prievaluate clinical trials vate services.

> The sample consisted of 30 patients, who met the following inclusion criteria: 18 years or older, on chemotherapy, using the SUS public service, and providing written consent.

Data collection was performed using a version of the European Organization for Research and Treatment of Cancer – Quality of Life Questionnaire Core-30 (EORTC QLQ-C30)(7), validated for the Brazilian population. The QLQ-C30 is a QOL instrument used in patients with cancer, and consists of 30 questions on five functional scales: physical, cognitive, emotional, and social functions, and role performance; three symptom scales: fatigue, pain, and nausea and vomit; one general health condition / QOL scale; and five other items that evaluate symptoms that cancer patients often complain about: dyspnea, loss of appetite, insomnia, constipation and diarrhea, plus an item that evaluates the financial burden caused by the disease and its treatment.

For the QLQ-C30 general health condition / QOL scales, and on scales regarding physical, emotional, cognitive and social functions, and role performance, scores closer to 100 meant the patient functioning was better or that these conditions had improved. On the other hand, scores closer to 100 on the symptom and financial burden scales meant an increased presence of the referred symptoms and difficulties.

The instrument was administered during the secondary adjuvant chemotherapy treatment, in the form of an interview, from April to November 2006.



The data were analyzed using SPSS for Windows. The reliability of the instrument was tested with Cronbach alpha  $(\alpha)$  internal consistency test.

For the descriptive data analysis, the mean and standard deviation values were calculated; an analysis of variance (ANOVA) was used to test the differences between the so-ciodemographic and clinical variables. In addition, the p-value was used, with 0.05 considered statistically significant.

The research was approved by the research ethics committee at Hospital das Clínicas de Ribeirão Preto at Faculdade de Medicina de Ribeirão Preto — University of São Paulo (HCRP-FMRP-USP), under register number HCRP 12483/2004. All information was kept confidential, and participants provided written consent, complying with the Brazilian Research Ethics Commission (CONEP) Resolution 196/96<sup>(8)</sup>.

## **RESULTS**

A Brazilian study<sup>(9)</sup> used and validated the QLQ-C30 for Brazilians, and the findings regarding the instrument's internal consistency for the sample used in the study was  $\alpha$ =0.86, which was considered reliable.

The present study sample consisted of 30 patients, residents in the Ribeirão Preto region, 50% females and 50% males. Most patients were more than 40 years, married, retired, and Catholic (Table 1).

 Table 1 - Sociodemographic characteristics - Ribeirão Preto - 2006

	Characteristics	N	%
Age group	40  — 60 years	15	50
	60  — 80 years	15	50
Marital status	Single	3	10
	Married	16	53.3
	Widowed	7	23.3
	Others	4	13.3
Profession	Health (university degree)	2	6.7
	Merchant / Cattle breeder	4	13.3
	Salesman / broker	1	3.3
	Agriculturist	1	3.3
	Driver	3	10
	Seamstress / Hairdresser	3	10
	Retired	16	53.3
Religion	Catholic	18	60
	Pentecostal	6	20
	Spiritualist	4	13.3
	Jehovah's Witness	1	3.3
	Buddhist	1	3.3

As for level of education, 27 (90%) of patients had complete or incomplete elementary level education; only one subject (3.3%) completed secondary-level education, and two (6.6%) completed superior education.

Regarding clinical characteristics, 16 (53.3%) participants had gastrointestinal cancer, 20% had breast cancer, one (3.3%) had prostate cancer, and seven (23.3%) were in metastasis.

In terms of therapy, 24 (80%) had undergone surgery to remove a tumor or for complete or partial removal of the affected organ and/or surrounding nodes; 11 (36.7%) patients underwent radiotherapy, eight underwent between one and 30 sessions, and three underwent more than 30 sessions.

The 30 patients were undergoing adjuvant chemotherapy treatment (i.e., after primary treatment – surgery and/or radiotherapy). Most patients began chemotherapy 10 months after receiving the diagnosis, 11 (36.6%) of which were undergoing the first chemotherapy cycle, and the other 19 (63.3%) were between the second and sixth cycle.

Table 2 shows the chemotherapy protocols used, of which 5-Fluorouracil (5-FU) was the most commonly used chemotherapy in 13 (43.3%) patients.

**Table 2** - Chemotherapy protocols used - Ribeirão Preto - 2006

Chemotherapy protocols used	N	%
5-Fluorouracil	13	43.3
5-Fluorouracil + Cyclophosphamide	1	3.3
5-Fluorouracil + Cisplatin	3	10
5-Fluorouracil+ Cyclophosphamide + Doxorubicin	3	10
5-Fluoroura cil + Cyclophosphamide + Metrotexate	2	6.7
Epirubicin + Cyclophosphamide	3	10
Cisplatin + Araceptin	1	3.3
Cisplatin + Taxol	1	3.3
Taxol	2	6.7
Oral chemotherapy	1	3.3

As for the chemotherapy side effects, five (16.7%) patients reported gastrointestinal complaints, such as nausea, vomiting, stomatitis, diarrhea, constipation, colic, and abdominal bloating; three (10%) reported physical symptoms like: uncomfortable heat, thirst, general sickness, weakness, sleepiness, insomnia, dizziness, pain, tremor, and itching; one (3.3%) patients reported emotional problems such as depression, anguish, and irritability; seven (23.3%) patients reported gastrointestinal and physical effects; four (13.3%) presented all three side effect types (gastrointestinal, physical, and emotional); and 10 (33.3%) patients were asymptomatic. These findings show that chemotherapy caused side effects in 20 patients, and that gastrointestinal side effects affected 16 patients.

On the QLQ-C30, the general health condition/QOL reached a 69.71 (Table 3), demonstrating that these patients consider they have a reasonable quality of life. The



physical, cognitive and social functions and role performance mean values ranged between 71.26 and 75.12, showing a satisfactory level. The mean emotional function was low (55.46), showing that patients were nervous, depressed, worried, and irritated.

**Table 3** - QLQ-C30 scales - Ribeirão Preto - 2006 (mean and standard deviation)

Scales	Mean	Standard Deviation
General health condition (GHC/QOL)	69.71	3.80
Physical function (PF)	72.24	5.00
Role performance (RP)	72.93	6.09
Emotional function (EF)	55.46	5.93
Cognitive function (CF)	71.26	6.33
Social function (SF)	75.12	5.68
Fatigue (FAT)	22.31	5.26
Nausea and vomiting (NAV)	9.44	3.36
Dyspnea (DIS)	10.55	5.08
Pain	23.33	6.11
Insomnia (INS)	34.44	7.23
Loss of appetite (LAP)	14.44	5.46
Constipation (CON)	12.21	4.65
Diarrhea (DIA)	0.0	0.0
Financial difficulties (FDI)	35.5	7.48

In the symptom scale, insomnia prevailed with a 34.44 mean, followed by pain with 23.33, fatigue with 22.31, loss of appetite with 14.44, constipation 12.21, dyspnea 10.55,

and nausea and vomiting with 9.44. It can be inferred that the presence of these symptoms affects the patients' physical, emotional, and cognitive functions, consequently affecting their mean global health measurement of 69.71.

As for the financial burden, the mean of 35.5 demonstrated that although the treatment for the disease is complex and costly, it had not posed major financial difficulties on patients, and that the SUS service had provided coverage for the whole treatment.

ANOVA results with the sociodemographic and clinical variables from the QLQ-C30 domains were significant with p-value  $\leq 0.05$  (Table 4).

Age was correlated with nausea and vomiting (NAV), insomnia (INS), and loss of appetite (LOP). This shows there is a significant difference between the age groups, with symptoms being stronger in the younger group, ranging in age from 40 to 60 years

The chemotherapy protocol was statistically significant ( $p \le 0.05$ ) with the INS and cognitive function scales (CF), and was highly significant ( $p \le 0.001$ ) with the pain, LOP, and constipation (CON) scales. This shows a significant difference among the chemotherapy protocols. It is observed that the greatest means occurred for the protocol of 5-Fluorouracil (5-FU) + Cyclophosphamide + Doxorubicin, showing that this protocol causes more side effects.

As for the diagnosis, the significant difference found with the LOP scale shows that patients with metastasis report a greater loss of appetite. The side effects reported by the patients were statistically significant with the CF scale, showing a greater mean for gastrointestinal side effects.



Table 4 - QLQ-C30 with the sociodemographic and clinical data - Ribeirão Preto - 2006

Scale	Socio-demographic variable	Variable	Mean	SD	P-value
NAV	Age group	40  — 60 years	64.28	99.96	0.029*
		60  — 80 years	4.44	11.72	
INS	Age group	40  — 60 years	384.33	446.25	0.045*
		60  — 80 years	104.41	262.11	
LAP	Age group	40  — 60 years	199.93	373.67	0.050*
		60  — 80 years	8.88	19.77	
Pain	CT Protocol	5FU + LV	56.35	140.81	0.001**
		5FU + Cycloph. + Doxo.	500.00	500.00	
		5FU + Cycloph. + Metrotexate	266.65	330.01	
		Epirubicin + Cycloph.	9.58	5.53	
		Taxol	208.15	176.56	
INS	CT Protocol	5FU + LV	17.93	29.21	0.002*
		5FU + Cisplatin	333.00	333.00	
		5FU + Cycloph. + Doxo.	555.33	509.10	
		5FU + Cycloph. + Metrotexate	33.30	47.09	
LAP	CT Protocol	5FU + LV	2.56	9.24	0.000**
		5FU + Cycloph. + Doxo.	555.33	509.01	
		5FU + Cycloph. + Metrotexate	16.65	23.55	
		Taxol	47.09	33.30	
CON	CT Protocol	5FU + LV	12.81	21.66	0.000**
		5FU + Cycloph. + Metrotexate	33.30	47.09	
		Epirubicin + Cycloph.	11.10	19.23	
CF	CT Protocol	5FU + LV	810.00	222.52	0.051*
		5FU + Cycloph. + Doxo.	500.00	500.00	
		5FU + Cycloph. + Metrotexate	1000.00	00.00	
		Epirubicin + Cycloph.	560.00	484.97	
		Taxol	166.50	235.47	
CF	Side	GI	1000.0	-	0.008*
	effects	Physical	890.00	190.53	
		Emotional	670.00	-	
		GI + Physical	478.57	355.17	
		GI + Physical + Emotional	335.00	410.97	

SD = standard deviation; CT = chemotherapy; 5-FU = Fluorouracil; LV = Leucovorin; Cycloph = Cyclophosphamide; Doxo = Doxorubicin; GI= gastrointestinal.  $^*p < 0.05$  is significant.  $^*p < 0.001$  is highly significant.

# **DISCUSSION**

The sociodemographic characteristics of the sample in this study portray the reality of patients attending the SUS: people with a low educational level from the Ribeirão Preto region. As for epidemiological aspects, this study is in agreement with the statistics that point out the cancer incidence rate for people with more than 40 years of age<sup>(1)</sup>.

Depending on the patient's age, there were significant differences in the NAV, INS, and LOP scales. It is likely that this is due to the protocols used, with 5-FU being the most commonly used drug in 13 (43.3%) patients, and toxol in two (6.7%) patients. These two drugs are considered having a moderate emetogenic effect. In order to classify the combination of the cytostatic drugs, the agent with the strongest emetogenic effect should be considered. Of the protocols in



this study, 5-FU was associated with drugs classified as having a moderate emetogenic effect, but at low dosages<sup>(10)</sup>.

Other factors besides the pharmacological characteristics should be taken into consideration as causes of nausea and vomiting, such as the patient's age, as this study showed that younger patients experienced more nausea and vomiting<sup>(3)</sup>. In the present study, a difference was found in patients in the younger age range between 40 and 60 years who reached greater means in the NAV, INS, and LOP scales.

As for the chemotherapy protocol, a significant difference was found in the pain, INS, LOP, CON, and CF scales. The 5-FU + Cyclophosphamide + Doxorubicin protocol presented greater means, indicating more symptoms, whereas smaller means were found in the CF scale with the Taxol protocol. This suggests that the referred drugs affect cognitive function. This result is likely associated to the strong emetogenic effect of Cyclophosphamide and Doxorubicin; therefore they cause more side effects, such as stomatitis, nausea and vomiting, and anorexia.

A studyperformed with patients that received at least two cycles of chemotherapy<sup>(11)</sup> showed that the patients presented changes in their taste and the most reported symptoms were: dry mouth, loss of appetite, nausea and vomiting, all of which were associated with the Cisplatin and Doxorubicin agents, which also caused a reduction in QOL.

In another study, 48% of the patients reported moderate constipation and 17% reported serious constipation  $^{(12)}$ . These symptoms were associated with the diagnosis of metastasis in seven (23.3%) patients, and with the diagnosis of gastrointestinal cancer in 16 (60%) patients.

The chemotherapy protocol also affected the CF. The protocols with the smallest means were Taxol and 5-FU + Cyclophosphamide + Doxorubicin and Epirubicin + Cyclophosphamide. This suggests that chemotherapy drugs have mechanisms that harm cognitive function.

The evidence cognitive dysfunction by chemotherapy drugs are shown in a study that reported that the mechanisms causing such harms are leukoencephalopathy and the inflammatory response in the brain, both induced by the responses of cytokines, anemia, and early menopause<sup>(13)</sup>.

Cognitive function is defined as a multidimensional concept and refers to the domains that result in a healthy performance of the brain, such as attention and concentration, executive and motor functions, processing fast information, language, visual and spatial ability, and memory<sup>(14)</sup>.

Chemotherapy is a systemic treatment with a strong impact on tumor cell division. It causes toxicity because of the deleterious effect it has on the body's normal cell division, such as the bone marrow or gastrointestinal tract. Neurotoxicity is a stronger side effect because the nervous system consists of cells that divide slowly or do not divide at all.

The protocols involved in this study are described as triggers of leukoencephalopathy (5-FU, Methotrexate,

Paclitaxel, and Cyclophosphamide) and inducers of the inflammatory process (Doxorubicin) that harm the cognitive function, causing, for instance, lack of concentration, reduced visual and spatial ability, and reduced memory<sup>(13)</sup>. The side effects also affected the CF, with the smallest means in patients with the strongest gastrointestinal, physical, and emotional symptoms. A previous study found an association between psychological factors, such as anxiety, stress, and depression, with a worse CF<sup>(15)</sup>. Another study found that mental or physical fatigue have a negative influence on CF<sup>(16)</sup>. Results from the present study were consistent with previous studies where the group with gastrointestinal, physical, and emotional side effects had the smallest CF means.

One study, which performed a two-year evaluation of the QOL and cognitive function cancer patients undergoing adjuvant CT, found that, in the beginning of the treatment, 30% of the patients presented moderate to serious cognitive impairment, which improved with time and dropped to 5% in the second evaluation, performed two years later<sup>(17)</sup>. There was also an improved general QOL.

The diagnosis was statistically significant in the LOP scale, as patients with metastasis had a greater mean in this scale. Loss of appetite is the second most frequent symptom in patients with advanced cancer, present in 65% to 85% of cases<sup>(18)</sup>.

It is crucial for nurses to evaluate the patient systematically, with close attention to the symptoms presented to identify changes in cognitive function. <sup>(19)</sup> It is essential for nurses to care for patients in the biological dimension and considering their subjectivity, observing the signs they transmit, and establishing empathy and emotional involvement using communication skills.

## CONCLUSIONS

This study evaluated the QoL in cancer patients with chemotherapy. In the last few decades, there has been a rise in the number of QoL studies in oncology, and, today, these studies are indispensible. One cannot think about increasing patient survival without increasing quality of life.

Measuring quality of life is a complex task because of its subjective and multidimensional characteristics,. Therefore, it is necessary to use validated and reliable instruments. In this study, it was possible to test the reliability of the EORTC QLQ-C30, which was a reliable and valid measure for QOL in cancer patients who were treated with antineoplastic chemotherapy.

As for the sociodemographic aspects, the study sample was homogeneous in terms of gender; most patients were 40 years or older, married, retired, Catholic, and with elementary education. Regarding clinical aspects, most patients had gastrointestinal cancer and had undergone surgery; all were in chemotherapy.



The findings showed that the most affected QOL domains were: insomnia, pain, and fatigue; as for the age group variable, there was a statistically significant difference in nausea and vomiting, insomnia, and loss of appetite in younger patients. Regarding the CT protocol, there were statistically significant differences for the domains: pain, insomnia, loss of appetite, constipation, and cognitive function; and, depending on the chemotherapy protocol, the signs and symptoms (CT side effects, such as nausea, vomiting, loss of appetite, and constipation were more common and had a negative effect on cognitive function.

Nurses should be aware about these effects and evaluate patients systematically using clinical instruments that are validated and reliable to detect changes to the patients'

cognitive function. In addition, it is important for nurses to identify the patients' risks to plan health care actions that include the prevention.

The results of the present study should be interpreted with care. The sample size is small and the cross-sectional design does not allow for evaluating the QOL changes through time. Therefore, the study cannot be generalized to the whole cancer population in chemotherapy. There is a need for longitudinal studies that measure the cancer patients' QOL as well as the impact of the treatment in daily life, because such studies would identify the aspects that require greater attention when planning the patients' physical, mental, and social rehabilitation. Hence, the present study can serve as an aid for health professionals in their practice.

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