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Quality of Life during chemotherapy: implications for social and legal medicine

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Summary. The impact of chemotherapy (CHT) on the Quality of Life (QoL) of cancer patients has been a topic of much concern in the relevant literature. In Italy, administrative legislation provides economic benefits for cases in which Italian citizens have been rendered incapable of performing their everyday activities. The present study is designed to assess the degree to which CHT affects the QoL of cancer patients by taking into account variables, such as age, gender or type of cancer, or whether assessment of QoL was performed either during or after chemotherapy, during active progressive disease, stable disease or disease response. The sample consisted of sixty-three patients receiving CHT (20/63 males and 43/63 females; age 18-87) whereas the control group consisted of fifty-eight cancer patients who did not receive CHT (36/58 males and 22/58 females; age 30-85). Odds ratios quantified the presence/absence of CHT with the presence/absence of activities of daily living (ADLs) in the cancer group populations. A statistically significant correlation was found between CHT and incapacity to perform ADLs (OR 5.28; CI 95%: 2.28-12.26; p <0.001), independent of age, gender or type of cancer.

Key words: disability, chemotherapy, activities of daily living (ADL)

«Qualità della vita durante la chemioterapia: implicazioni medico sociali e medico legali»

Riassunto. L'impatto della chemioterapia (CHT) sulla qualità della vita (QoL) dei pazienti oncologici è molto discussa in letteratura. In Italia la normativa prevede benefici economici nel caso di cittadini con incapacità nello svolgimento degli atti quotidiani della vita. Lo studio è stato progettato per valutare la misura in cui la CHT incida sulla QoL dei pazienti oncologici anche in funzione di variabili come età, sesso o tipo di tumore, o se la valutazione della QoL è stata effettuata durante o dopo la terapia, nella fase attiva della patologia o di stabilità o risposta alla terapia. Il campione è costituito da sessantatre pazienti che hanno ricevuto la chemioterapia (20/63 maschi e 43/63 femmine; età compresa tra 18-87 anni) mentre il gruppo di controllo di cinquattotto pazienti oncologici non in chemioterapia (36/58 maschi e 22/58 femmine; età compresa tra 30-85 anni). Odds Ratio misurato la presenza/assenza di CHT con la presenza/assenza di atti della vita quotidiana nella popolazione con neoplasia. Esiste un'associazione statisticamente significativa tra chemioterapia ed incapacità nello svolgimento degli atti quotidiani della vita (OR 5.28; CI 95%: 2.28-12.26; p <0.001) indipendentemente da età, genere o tipologia di tumore.

Parole chiave: disabilità, chemioterapia, attività della vita quotidiana

Introduction

In Italy, patients who are incapable of dealing with the Activities of Daily Living (ADL) due to pathological circumstances, such as chemotherapy (CHT) receive economic support.

The multifactorial evaluation concerning whether or not they are capable or incapable of ADL is carried out by a medical committee composed of specialists in various branches and a chairperson who is a specialist in legal medicine. In addition to 'type of disease', factors considered include the impact of debility upon patient autonomy, functional capacity and essential aspects of ADL such as the ability to eat, dress, take care of personal hygiene, etc.

Currently, many studies have addressed the Quality of Life (QoL) issues of patients with chronic pathologies (1) and the ADL of oncologic patients (2, 3) with particular attention to the levels of distress (4, 5), fatigue (6), nausea, vomiting, diarrhea and loss of appetite (7) that they display. Many psychopathological factors are also recognizable, such as depression, anxiety and sleep problems, e.g. loss, quality, etc (8).

Probably, the CHT process, in itself, is the most important factor that determines the QoL of oncologic patients (9), by influencing the physical (10, 11) and psychosocial (12) wellness of the patient. Despite the interest generated in the literature regarding QoL issues (13, 14), there exist both problems and inconsistences limiting the utility of the prevailing diagnostic evaluation and relating to the timing of evaluation. Chemotherapy is associated with short- or long-term effects, implying that the distance of the point of evaluation from the time of CHT administration becomes an essential variable. The estimation of CHT influence upon QoL depends on whether the measurements are performed immediately after CHT or following a delay. The later the estimates are performed, the greater the probability that QoL has deteriorated (due to continued development of disease pathology), independent of 'time of estimation'.

Nevertheless, no unanimous agreement exists on the timing and the actual incidence of chemotherapy. Important symptoms such as fatigue, constipation or loss of appetite may appear as little as one week after CHT (15), although it has been argued that CHT induces only a partial effect on QoL, during and after treatment (16), and up to one year (17, 18). It is still debated whether or not there is an association between QoL and CHT in the fifth year (19, 20). Some studies support the lack of association between CHT and QoL (21, 22), others indicate that CHT affects QoL but this is clinically expressed only some years after treatment (23, 24). According to Arndt *et al.* (25), it becomes apparent 1-3 years after diagnosis in patients who received CHT (25). The type of CHT applied constitutes another important variable in relation to its specific effects in the short and long-term. However, the effects of CHT on QoL also depend upon the frequencies of the CHT cycles and their duration.

The present study measured CHT as a risk factor for the extent of cancer patient disability, determining the performance of ADLs and whether or not these values are affected by variables such as age, gender or type of tumor.

Methods

The sample was composed of 63 patients (20/63 males and 43/63 females; age 18-87) selected according to the following criteria: disease (cancer), therapy (ongoing CHT, no radiotherapy) (Table 1). During the period between July 1 (2013) and June 30 (2014) they underwent medico-social evaluation of disability in ADL by the committee concerned.

Sample selection and collection of clinical data and the results of the legal-medicine committee (ability or disability in ADL without reference to tests or scales) made by five doctors who had followed their patients' process of application were included subsequently in the study.

The control group was composed of 58 cancer patients (36/58 M and 22/58 F; age 30-85) not in ongoing CHT, who underwent the same assessment in the same period and in the same manner (Table 1).

The prevalence of cancer in the two groups was highest for breast cancer in women (29/65) and colorectal cancer in men (11/56).

The patients were selected consecutively during the study enrollment period. Specifically, we asked whether or not there had occurred a deterioration in

Table 1. The gender, age and type of cancer presented by the patient and the control group (patients on chemotherapy and patients not on chemotherapy, CHT) in the assessment of activities of daily living (ADLs).

Patients on CHT				Patients not on CHT			
Gender	Age	Organ/Type	ADL*	Gender	Age	Organ/Type	ADL*
F	78	Myeloma	N	F	58	Colon	Y
M	68	Colon	N	M	30	Testicle	Y
M	67	Myeloma	N	M	50	Leukemia	Y
F	78	Breast	N	F	62	Breast	Y
M	83	Colon	N	F	64	Utero	Y
F	56	Breast	N	M	75	Stomach	N
F	62	Breast	Y	F	61	Breast	Y
F	56	Lung	N	M	38	Kidney	Y
F	73	Breast	N	F	64	Cholecyst	Y
F	53	Colon	N	M	61	Lung	Y
F	54	Breast	Y	M	48	Liver	N
F	52	Lymphoma	N	F	41	Epiglottis	Y
M	76	Leukemia	N	F	44	Breast	Y
M	32	Lymphoma	N	M	46	Skin	Y
F	38	Lymphoma	N	M	54	Colon	Y
F	37	Breast	Y	F	47	Utero	Y
F	36	Breast	Y	F	45	Breast	Y
F	50	Breast	N	M	60	Lung	Y
M	42	Colon	N	F	50	Breast	Y
F	18	Leukemia	N	F	56	Breast	Y
F	49	Breast	Y	F	46	Thyroid	Y
F	49	Breast	N	M	85	Pleura	N
F	49	Breast	N	M	73	Stomach	N
M	28	Lymphoma	Y	M	70	Lung	N
M	58	Colon	Y	M	53	Vocal cords	Y
F	61	Colon	Y	M	80	Colon	Y
M	64	Prostate	Y	M	69	Colon	Y
F	64	Leukemia	N	F	68	Breast	Y
F	63	Lung	Y	F	42	Stomach	Y
F	63	Breast	N	F	50	Breast	Y
F	50	Thyroid	Y	M	60	Thyroid	Y
F	49	Leukemia	Y	M	77	Kidney	Y
F	56	Bladder	Y	M	82	Lung	Y
F	51	Breast	N	F	36	Utero	Y
F	74	Pancreas	N	M	66	Breast	Y
F	63	Ovary	N	M	79	Skin	Y
F	61	Colon	Y	M	75	Prostate	Y
F	54	Lung	N	M	76	Larynx	Y
M	64	Lymphoma	N	M	68	Colon	Y
M	47	Kidney	N	M	71	Prostate	Y
M	65	Prostate	N	M	70	Urethra	Y
F	68	Breast	Y	M	74	Prostate	Y
F	69	Breast	Y	M	82	Prostate	Y
M	66	Bladder	Y	F	75	Breast	Y
F	66	Colon	Y	M	69	Prostate	Y
M	71	Bladder	Y	M	66	Colon	Y
F	73	Breast	Y	F	66	Bladder	Y
F	75	Myeloma	Y	M	70	Muscle	Y
M	68	Mouth	Y	F	74	Breast	N

(continued)

Table 1 (continued). The gender, age and type of cancer presented by the patient and the control group (patients on chemotherapy and not on chemotherapy, CHT) in the assessment of activities of daily living (ADLs).

Patients on CHT				Patients not on CHT			
Gender	Age	Organ/Type	ADL*	Gender	Age	Organ/Type	ADL*
F	87	Kidney	Y	M	58	Penis	Y
F	67	Pleura	Y	M	76	Lung	N
F	78	Lymphoma	Y	M	58	Colon	Y
M	71	Colon	Y	F	42	Breast	Y
F	72	Utero	Y	F	48	Colon	Y
F	67	Myeloma	Y	M	47	Testicle	Y
F	63	Ovary	N	M	83	Skin	N
F	43	Leukemia	Y	M	83	Prostate	N
M	76	Bladder	N	F	65	Parotid	N
M	63	Stomach	Y				
F	74	Ovary	N				
M	22	Lymphoma	N				
F	59	Breast	N				
M	73	Lung	N				

*ADL = ability to perform the Activities of Daily Living.
Y=Yes; N=No

ADL for patients that received CHT (the patient sample) compared to the previous time as well as patients with no-CHT (patient control group).

ADLs were evaluated on both basic (eating, dressing, personal care and hygiene, moving aboout the house) and instrumental (use of cooking and housework appliances, autonomy when moving outside the house or in taking drug therapy) levels.

Following collection of the results of the medico legal evaluation, the association (Odds Ratio: OR – simple logistic regression) between CHT and disability in ADL for the assessment of variables such as sex, age and type of tumor (Table 2) was evaluated by software MedCalc.

Results

The study showed a significant association (OR 5.28; CI 95%: 2.28-12.26, p <0.001) between CHT and disability in ADL (ADL disability in sample 52.4% *vs* 17.2% in control group) thereby justifying the award of economic support.

This association was verified in the gender variable (Table 3), for both male (ADL disability in sample 60% *vs* 22.2% in control group) (OR 5.25; CI 95%: 1.60-17.27; p <0.01) and female (ADL disability in sample 48.8% *vs* 9.1% in control group) (OR 9.55; CI 95%: 1.98-45.96; p <0.005) patients.

The evaluation of capacity during CHT was not conditioned by age (Table 3): <50 years (ADL disability in sample 56.2% *vs* 5.9% in control group) (OR 20.57; CI 95%: 2.17-194.95; p <0.01), 51-65 years (ADL disability in sample 59.1% *vs* 7.1% in control group) (OR 18.78; CI 95%: 2.07-170.22; p <0.01) and >66 years (ADL disability in sample 44% *vs* 18.5% in control group) (OR 1.87; CI 95%: 0.60-5.85; p <0.5).

This association was also verified in the most frequently observed cancers, such as breast cancer (ADL disability in sample 52.9% *vs* 8.3% in control group) (OR 12.38; CI 95%: 1.29-118.34; p <0.05) and colorectal cancer (ADL disability in sample 44.4% *vs* 0% in control group) (OR 13.91; CI 95%: 0.62-312.62; p<0.1) (Table 3).

Discussion

CHT presents a risk factor that impacts upon QoL and judgment regardless of differences in the

Table 2. Comparison of patient characteristics between the two groups of patients (see Table 1).

Gender					
Patients in CHT			Patients not in CHT		
M	F		M	F	
20	43		36	22	
Age					
Patients on chemotherapy			Patients not on chemotherapy		
<50	51-65	>66	<50	51-65	>66
16	22	25	17	14	27
Organ					
Patients on CHT			Patients not on CHT		
Bladder	4		Bladder	1	
Breast	17		Breast	12	
Cholecyst	0		Cholecyst	1	
Colon	9		Colon	8	
Epiglottis	0		Epiglottis	1	
Kidney	2		Kidney	2	
Larynx	0		Larynx	1	
Leukemia	5		Leukemia	1	
Liver	0		Liver	1	
Lung	4		Lung	5	
Lymphoma	7		Lymphoma	0	
Mouth	1		Mouth	0	
Muscle	0		Muscle	1	
Myeloma	4		Myeloma	0	
Ovary	3		Ovary	0	
Pancreas	1		Pancreas	0	
Parotid	0		Parotid	1	
Penis	0		Penis	1	
Pleura	1		Pleura	1	
Prostate	2		Prostate	6	
Skin	0		Skin	3	
Stomach	1		Stomach	3	
Testicle	0		Testicle	2	
Thyroid	1		Thyroid	2	
Urethra	0		Urethra	1	
Utero	1		Utero	3	
Vocal cords	0		Vocal cords	1	

variables considered, i.e. age, gender and type of tumor.

There exists a plethora of references dealing with gender effects in this regard (26). For example, in surgery, this is observed in cases of curative resectioning of colorectal cancer in women who show a better survival outcome (26, 27). The effectiveness of cytoreductive surgery and heated intraperitoneal CHT in metastatic cancers of the appendix have associated the female gender with superior outcomes for long-term survival (28, 29).

Table 3. Odds Ratio analyses by gender, age and type of organ.

		OR	95% CI	p value
Gender	Male	5.25	1.60-17.27	<0.01
	Female	9.55	1.98-45.96	<0.005
Age	<50	20.57	2.17-194.95	<0.01
	51-65	18.78	2.07-170.22	<0.01
	>66	1.87	0.60-5.85	<0.5
Organ	Breast	12.38	1.29-118.34	<0.05
	Colon	13.91	0.62-312.62	<0.1

OR: Odds ratio
CI: confidence interval

Gender influences both the efficacy of CHT and managing adverse effects (30). The efficacy of antiemetic treatment (ondansetron with dexamethasone and aprepitant), in addition to CHT, showed a higher response rate in males and >55 years than females, with greater variability in women and juveniles showing increased CHT-induced nausea and vomiting risk (30). The incidence of nausea and vomiting is higher in female patients and is linked to their level of education (31). The number of patients who displayed inferior pharmacological control of vomiting both acute, and in delayed form (32, 33), and the rate of complete control of nausea and vomiting were significantly lower in women than in men (34).

The legal-medicine diagnosis was not influenced by age. Nevertheless, elderly patients are particularly vulnerable to the toxicity of the treatment, resulting in decreased QoL and deterioration of physical function. This circumstance may be due to the long periods of hospitalization, increased risk of infection, and the presence of additional comorbidities. In addition, aging is linked to significant decreases in physiological functions in a large range of cells, tissues, organs and physiological systems (35, 36). These factors imply that patients of advanced age receive less intensive cancer therapy than younger patients; which is the case even if the patients are highly functional and do not present comorbidities (37). Consequently, elderly patients are often undertreated (38, 39).

The legal-medicine diagnosis is not influenced by the type of cancer. In the case of late diagnosed cancer and those forms that do not permit radical treatment (40), the patient feels himself/herself to be "condemned" and may develop a depressive state that drastically changes his/her life both physically and in family and social relationships (41). These cancers (42) are characterized by their aggressiveness and high mortality rates due to anatomical characteristics implicating 'failure-to-detect' the first signs of cancer by both the patient and the doctor (43). Zabora *et al.* compared fourteen cancers in 4,496 patients and drew up the following classification in terms of decreasing levels of distress: lung, brain, Hodgkin's lymphoma, pancreatic lymphoma, liver, head and neck, adenocarcinoma, breast, leukemia, melanoma, colon, prostate and gynecological cancer (44). Variables not taken into consideration include the staging of cancers and the type of CHT. Cancer staging, in particular surgical staging (45), is reflected in the types of treatment and hence in their effects on QoL (46). An early-stage tumor is likely to have a more favorable outcome prognosis.

Regarding the type of CHT applied, consideration of the specific type of drug/medicine was not made although it should be said that it deserves to be the topic of an analysis on how CHT influences QoL. Maneechawakajorn and Suksuperm (47) conducted a study on eighty-eight patients with non-small cell lung cancers and CHT using 'old style' therapy (platinum associated with etoposide) and 'new style' (platinum associated with paclitaxel/gemcitabine); they evaluated the QoL by the Functional Assessment of Cancer Therapy-Lung Cancer, arriving at a similar score, except for a slight decrease in social / family wellness. Finally, Verhaar *et al.* found no differences in hospital-related QoL and disease-specific symptoms between patients treated with surgery alone versus surgery+adjuvant CHT in both younger and elderly colon cancer patients (48).

Conclusion

CHT in cancer patients influences the medical assessment of whether to award economic support as per Italian law, without any significant differentiation according to factors including age, gender or type of cancer.

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