

Predictors of quality of life in patients with skin melanoma at the Dermatology Department of the Porto Alegre Teaching Hospital *

Preditores de qualidade de vida em pacientes com melanoma cutâneo no serviço de dermatologia do Hospital de Clínicas de Porto Alegre

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Abstract: **BACKGROUNDS:** Some symptoms present in melanoma patients are directly related to psychological stress, which emphasizes the need to evaluate quality of life (QoL) in these patients at all the stages of their disease. **Objectives:** The objective of this study was to evaluate quality of life in a sample of patients diagnosed with melanoma, using the Functional Assessment of Cancer Therapy-General (FACT-G) questionnaire.

METHODS: A descriptive, cross sectional study was conducted between July and December, 2006 with all patients with skin melanoma receiving follow-up care at the Department of Dermatology of the Porto Alegre Teaching Hospital, Federal University of Rio Grande do Sul.

RESULTS: Sixty patients were included in the study. Mean age was 55.6 years. Poor education level (primary school or less) was associated with a poorer FACT-G score. Patients with a family history of the disease had higher QoL scores in 3 of the 4 categories evaluated: physical, emotional and functional wellbeing ($p < 0.01$). QoL scores were higher in married patients (82.42) compared to single patients (70.28) ($p < 0.01$). Patients with metastases had lower scores in the functional wellbeing category and this difference was statistically significant.

CONCLUSIONS: Factors related to the tumor, as well as gender, age and employment status, were not found to be predictive of quality of life in this sample. Quality of life scores were lower in the functional wellbeing domain in patients with metastases. Married patients are able to count on greater comfort and emotional support to help them deal with the diagnosis of melanoma. Patients with a family history of melanoma had significantly higher quality of life scores, while those with poor education levels had lower scores.

Keywords: Dermatology; Quality of life indicators; Oncology; Melanoma; Quality of life;

Resumo: **FUNDAMENTOS:** Alguns sintomas presentes nos pacientes com melanoma estão diretamente relacionados à tensão psicológica, o que reforça a necessidade de avaliar a qualidade de vida em todas as fases da doença.

OBJETIVOS: Avaliar a qualidade de vida dos pacientes diagnosticados com melanoma por meio do questionário Fact-G.

MÉTODOS: Estudo descritivo transversal que incluiu todos os pacientes em seguimento no serviço de dermatologia do Hospital de Clínicas de Porto Alegre entre julho e dezembro de 2006.

RESULTADOS: Sessenta pacientes foram incluídos. A idade média foi de 55,6 anos. O nível de escolaridade até primeiro grau foi correlacionado a escores mais baixos no Fact-G. Os pacientes com história familiar apresentaram maiores escores de QoL em três das quatro categorias avaliadas: bem-estar físico, emocional e funcional ($P < 0,01$). Pacientes casados mostraram melhor qualidade de vida (82,42) que os solteiros (70,28; $P < 0,01$). Os pacientes com metástase obtiveram uma menor pontuação no questionário no domínio bem-estar funcional.

CONCLUSÕES: Os fatores relacionados ao tumor, assim como o sexo, a idade e a situação de emprego, não foram preditores de qualidade de vida. Pacientes com metástases apresentaram pior qualidade de vida no domínio bem-estar funcional. Pacientes casados têm mais conforto e apoio emocional para lidar com o diagnóstico do tumor. Os pacientes com história familiar de melanoma tiveram melhor qualidade de vida e os com baixa escolaridade, uma pior qualidade de vida.

Palavras-chave: Dermatologia; Indicadores de qualidade de vida; Melanoma; Oncologia; Qualidade de vida

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INTRODUCTION

Skin melanoma is a fast-growing malignant tumor of the melanocytes. Although it represents only 4% of cases of skin tumors, it is responsible for more than 79% of deaths from skin cancer.^{1,2} The incidence of this type of tumor has increased considerably in recent years.³⁻⁵

A total of 2,960 new cases of skin melanoma are expected in men and 2,970 in women in 2010 according to the Estimates of Cancer Incidence in Brazil. The south of the country is the region in which prevalence is highest.⁶ According to the American Cancer Society, more than 55,000 new cases of skin melanoma will be diagnosed in the United States each year and approximately 8,000 individuals will die of the disease.⁷

Patients should be followed up for at least five years following surgery. Clinical and laboratory follow-up should be carried out at intervals that vary in accordance with the stage of the tumor to evaluate the presence of metastases.⁸ In the first years of the disease, the principal objective of follow-up is to detect locoregional recurrence, since during this phase there is still a perspective of radical treatment with the intention to cure.⁹ Later, the detection of distant metastases by laboratory or imaging exams is of little benefit, since the perspectives of treatment and cure are extremely limited.⁹

Quality of life (QoL) is a broad term that involves issues such as social well-being, health and the insertion of the individual in the family and in society, among others.^{10,11} The expression "quality of life" was defined by the World Health Organization's Quality of Life Group as: "an individual's perception of their position in life in the context of the culture and value system where they live, and in relation to their goals, expectations, standards and concerns" (World Health Organization).¹²

The health/sickness ratio is multidimensional, involving physical, emotional, functional, social and cognitive factors, and is also associated with discomfort and somatic symptoms caused by the disease and its treatment.¹³ The term "health-related quality of life" (HRQoL) relates a better or poorer QoL to the state of health/sickness of the individual.¹⁴

Evaluation of QoL has already been used in medicine for some years to measure to what extent the results obtained fulfill the fundamental objectives of prolonging life, alleviating pain, restoring function and preventing disabilities.^{15,9} This assessment is important when making decisions in clinical practice.¹⁶

HRQoL is measured with the use of an instrument that subjectively quantifies the impact of the disease and the outcome of treatment on psychic, psychological, social and economic aspects and on the

well-being of patients.¹⁷ These instruments should assess the way in which the individual feels about the disease and how he/she deals with it.¹⁸ In this paper, QoL will be used to refer to HRQoL, since the former is the term most commonly used in the literature.

Following a diagnosis of cancer, patients experience negative feelings of anger, anguish and fear, principally the fear of death, of suffering, of recurrence of the disease and of physical and financial limitations. The need for support and care is already known to constitute a key feature in the treatment of cancer patients.¹³

The presence of some symptoms such as pain, malaise and tiredness is known to be directly related to psychological anguish and low quality of life in these patients, emphasizing the need to evaluate QoL at all stages of the disease. This evaluation should also be used to predict the progress of treatment, which directly affects patients' survival.^{19,20}

In some sub-groups of patients, melanoma, in addition to being a devastating disease with significant lethality, may also involve a stigma because of its appearance when the lesion is located on exposed areas of the skin in patients with this condition.²¹

After receiving a diagnosis of skin melanoma, approximately 3% of patients will develop a second melanoma within a period of three years after the initial diagnosis. The risk may be greater in patients with a family history of melanoma, with a 33% incidence of a second melanoma in a 5-year follow-up period.⁹ These factors may generate much anxiety and may alter patients' quality of life.⁹

Excessive testing during patient follow-up, in addition to showing no advantage with respect to the treatment of patients, may exert psychological effects on the individuals. As the dates of laboratory and imaging tests approach in the five years following diagnosis of a skin melanoma, patients often experience anxiety and anguish associated with waiting for the results.^{22,23}

No studies were found in the Medline, Lilacs or Cochrane databases in which the QoL of patients with skin melanoma was evaluated in Brazil. The only studies found involved patients with uveal melanoma.²⁴

The objective of the present study was to evaluate quality of life (QoL) and its predictors in patients with a diagnosis of skin melanoma undergoing follow-up at the dermatology clinic of the Porto Alegre Teaching Hospital with the use of a questionnaire that had been previously translated into Portuguese and validated for use in this language (the Functional Assessment of Cancer Therapy General Scale – FACT-G).

MATERIAL AND METHODS

For this cross-sectional study on quality of life, all the patients with a diagnosis of skin melanoma being followed up at the dermatology clinic of the Porto Alegre Teaching Hospital between July and December 2006 were enrolled, irrespective of gender or age.

The inclusion criteria consisted of: patients with a diagnosis of skin melanoma who had already undergone surgery to remove the lesion, who were aware of their diagnosis and who were in follow-up at this dermatology clinic; patients who had been diagnosed with skin melanoma more than six months and less than five years previously; and patients at any stage of the disease irrespective of the presence of metastases, Breslow thickness or treatment with chemotherapy or immunotherapy.

Patients were excluded from the study if histopathology failed to confirm their lesion as a skin melanoma or if there was any doubt regarding diagnosis; patients with any other severe concomitant chronic disease in addition to the skin melanoma; and patients with other types of cancer as well as the melanoma.

All the patients were interviewed by the same interviewer, the principal investigator, using the 27-item Functional Assessment of Cancer Therapy General Scale (FACT-G), version 4, which has already been translated into Portuguese and validated for use in this language (www.facit.org), to evaluate the quality of life of patients and deal with their principal concerns. The FACT-G is subdivided into 4 domains: physical well-being, social/family well-being, emotional well-being and functional well-being (Graph 1).

Each item in the questionnaire is answered by selecting one of the following options: not at all = 0; a little bit = 1; somewhat = 2; quite a bit = 3; or very much = 4. The maximum score obtained is 108 points, divided into 4 domains: physical well-being (7 items), social/family well-being (7 items), emotional well-being (6 items) and functional well-being (7 items). The request to use the questionnaire was made through www.facit.org and use was authorized under request number 439.

Participation was voluntary and all the patients interviewed signed an informed consent form, which is part of the study protocol approved by the Internal Review Board of the Porto Alegre Teaching Hospital. To avoid biases, the questionnaire was applied at an interview by the same person, the principal investigator, in all cases and in accordance with the recommendations of the FACIT system. All interviews took place in the doctor's office on the day of a normal clinical follow-up visit by the patient to the dermatology clinic of the Porto Alegre Teaching Hospital.

Other data obtained from the patients' medical charts were also evaluated, such as: gender, age, employment, education level, site of the primary lesion, date of diagnosis, family history of melanoma, Clark's level, Breslow thickness, the presence or absence of metastases and treatment. The data from the charts were always collected after the interview to ensure that the interviewer was not influenced by the data.

After the data had been collected, patients with low QoL scores or any who were interested were offered individual psychological support or participation in psycho-educational support groups with doctors and psychologists, while those requiring further information on their disease were offered more frequent dermatological consultations (extra appointments in addition to the usual patient follow-up). Scores 7 points below the mean score for the general population were considered low, as defined by Cella et al.¹⁹

DATA ANALYSIS

The scores were obtained in accordance with the formula that had been previously established by the FACIT system and was supplied together with the questionnaire (Graph 1). The scores for each domain are added, multiplied by the number of questions and divided by the number of items answered (since the patients may opt not to answer any given item). The domains are then added to give the final result, the Trial Outcome Index (TOI).

Total score: PWB + SWB + EWB + FWB = TOI

Physical well-being (PWB); social/family well-being (SWB); emotional well-being (EWB); functional well-being (FWB).

Means and standard deviations were used to describe all the domains (physical well-being, social/family well-being, emotional well-being and functional well-being). The data were tabulated using the SPSS statistical software program, version 14.0 and possible associations between quality of life and the following variables were analyzed: gender, age, education level, marital status, employment, time since diagnosis of melanoma, family history of melanoma, site of the tumor, Breslow thickness, Clark's level, clinical and pathological type, presence or absence of metastases and whether or not there had been a recurrence of the lesions.

For continuous variables such as age and Breslow thickness, Pearson and Spearman correlation coefficients were used, respectively. For dichotomized variables (gender, marital status,

CHART 1: The Functional Assessment of Cancer Therapy General Scale (FACT-G), version 4*

		Not at all	A little bit	Some-what	Quite a bit	Very much
PHYSICAL WELL-BEING						
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family.	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed during the day	0	1	2	3	4
SOCIAL/FAMILY WELL-BEING						
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
GS7	Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box and go to the next section. I am satisfied with my sex life.	0	1	2	3	4
EMOTIONAL WELL-BEING						
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse.	0	1	2	3	4
FUNCTIONAL WELL-BEING						
GF1	I am able to work (including housework)	0	1	2	3	4
GF2	My work (including housework) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I sleep well	0	1	2	3	4
GF6	I enjoy the things I usually do for fun.	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

*You will find a list of statements that other people who have the same disease as you do considered important. Please circle the number that best describes your health status during the previous 7 days.

Source: With the permission of: www.fact.com, 76 following acceptance of registration (registration number: 439)

employment, family history of melanoma, metastases, recurrence), Student's t-test was used to compare the mean QoL scores. For the other variables, analysis of variance (ANOVA) was used to compare means. Significance level was established as $p \leq 0.05$.

The variation in QoL scores was also evaluated in accordance with the pre-established minimal important differences (MID) for the scores obtained in the FACT-G scales or sub-scales. An MID is the least difference in score in any given domain that the

patients perceive as being important, whether beneficial or prejudicial.

RESULTS

Of the 63 patients with skin melanoma undergoing follow-up at the dermatology clinic of the Porto Alegre Teaching Hospital between July and December 2006, one patient refused to participate in the study and another two were excluded because they had comorbidities: one had severe pulmonary emphysema

and the other had mild mental retardation and difficulty in understanding. Therefore, a total of 60 patients were included in the study: 24 men and 36 women. The mean age of patients was 55.63 years. Only 10% of the patients had a family history of melanoma.

The great majority of the individuals interviewed were married (73.3%), had no more than primary education (60%) and were currently employed (61.7%) (Table 1).

The most common clinical-pathological type was superficial spreading melanoma (43.3%), followed by nodular melanoma (28.3%) and lentigo-maligna melanoma (13.3%). Only two patients had an acral lentiginous melanoma and in three other cases the type of melanoma was not classified. Median Breslow thickness was 2 mm, with an interquartile range of 0.6 – 8.41. The tumor was most commonly situated on the trunk, members or head/neck, respectively.

Fifteen patients had metastases and in eight cases the disease had recurred at the site of the primary tumor or in another location (*de novo*).

The maximum score obtained in the questionnaire was 98 points and the minimum 23 points (mean = 79.2; standard deviation = 16.6). The scores obtained were analyzed with the sociodemographic variables and with the characteristics of the tumor using the SPSS statistical software program,

TABLE 1: Sociodemographic variables of the patients in the sample *

Variables	n	%
<i>Gender</i>		
Male	24	40%
Female	36	60%
<i>Employment</i>		
Employed	37	61,7%
Unemployed	3	5%
Retired	16	26,7%
Student	1	1,7%
<i>Marital status</i>		
Married	44	73,3%
Unmarried	16	26,4%
<i>Family history</i>		
Positive	6	10%
Negative	41	68,3%
Unknown	13	21,7%

* Some variables do not add up to 100%, since not all data were available for all the patients in the study

version 14.0.

The patient's age was weakly correlated with quality of life scores (Pearson correlation coefficient: 0.084). No statistically significant correlation was found between quality of life and the patient's education level or employment status. No association was found with gender, men and women having very similar mean scores: 79.73 and 78.9 points, respectively.

Patients with a family history of melanoma (first-degree relatives) had higher QoL scores compared to patients with no cases of skin cancer in the family. Mean overall score was 91.72 for patients with a family history compared to 77.85 for the group with no cases of melanoma in the family ($p=0.000$; 95% confidence interval [95%CI]: 7.9-19.86). It should be emphasized, however, that the number (n) of patients with a family history of melanoma was small, only 6 cases. When the domains of the questionnaire were analyzed separately, significance was found with respect to physical well-being ($p=0.000$; 95%CI: 2.51 – 7.36), emotional well-being ($p=0.000$; 95%CI: 1.92 – 5.75) and functional well-being ($p=0.032$; 95%CI: 0.42 – 9.22). No significant association was found for social/family well-being (Figure 1).

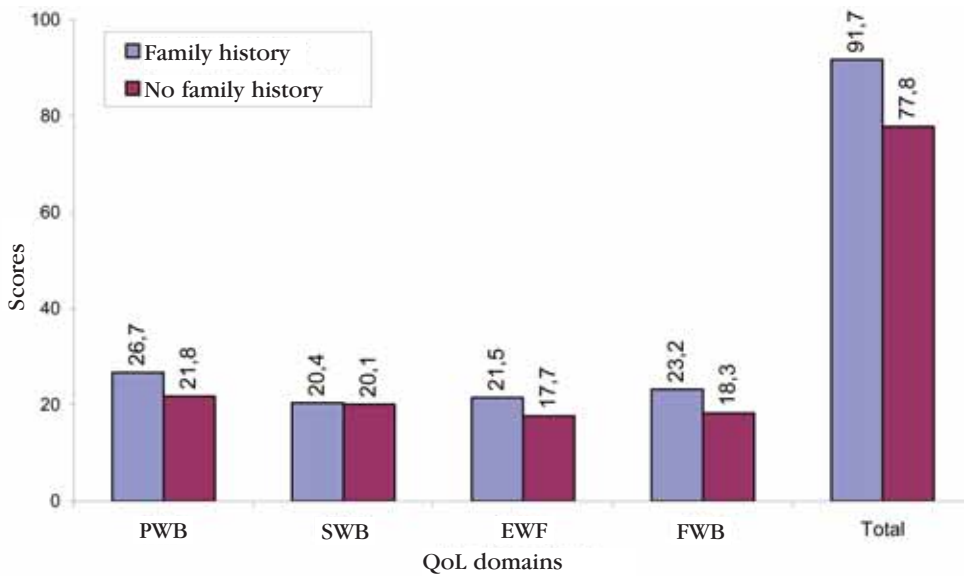
With respect to the patient's marital status, being married was found to be an important predictor of good quality of life, with mean scores of 82.42 for married patients and 70.28 for unmarried individuals (single, widowed or separated) ($p=0.011$; 95%CI: -21.4 to -2.9). Significance was also found within the domains of physical well-being ($p=0.022$; 95%CI: -7.2 to -5.7); emotional well-being ($p=0.002$; 95%CI: -6.9 to -1.7) and functional well-being ($p=0.009$; 95%CI: -7.3 to -1.0). No significance was found for social/family well-being (Figure 2).

There was no statistically significant difference in the overall score of the questionnaire between the patients who had received a diagnosis of metastatic melanoma and those who had not ($p = 0.076$); however, when the domain *functional well-being*, which encompasses items such as sleep quality and capacity for work and enjoyment, was analyzed, the score was lower for the group of patients with metastases ($p = 0.026$; 95%CI: -8 to -0.6) (Figure 3).

Analysis of the minimal important difference (MID) for the overall score and for the scores in the sub-scales of the FACT-G questionnaire also showed a poorer QoL score for all the domains for those individuals who did not live with a partner.

Comparing the individuals with skin melanoma who had only primary education with those who had a university education, a difference greater than the estimated MID was found.

Patients who had been diagnosed less than one year previously had a poorer score in the QoL ques-



GRAPH 1: Correlation between scores in the FACT-G quality of life questionnaire and a family history of melanoma

Physical well-being (PWB); social/family well-being (SWB); emotional well-being (EWB); functional well-being (FWB).

tionnaire, with a difference of 5 points in TOI, a greater difference than the MID (3 points).

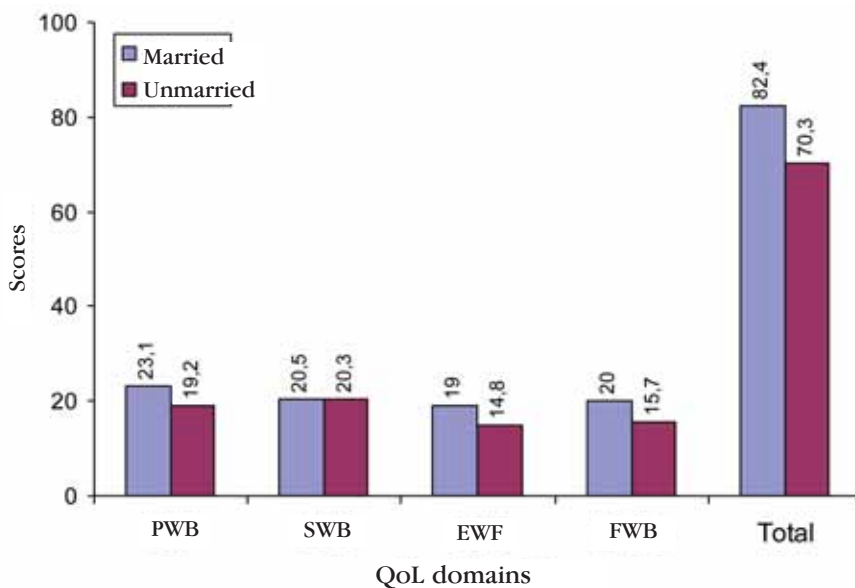
The presence of metastases reduced QoL scores (more than estimated MID) in all the domains with the exception of emotional well-being.

DISCUSSION

In clinical practice, the potential use of QoL instruments may be useful for the identification of suspected cases of psychological stress and to describe the information obtained from the various domains through the use of multidimensional questionnaires.²⁵

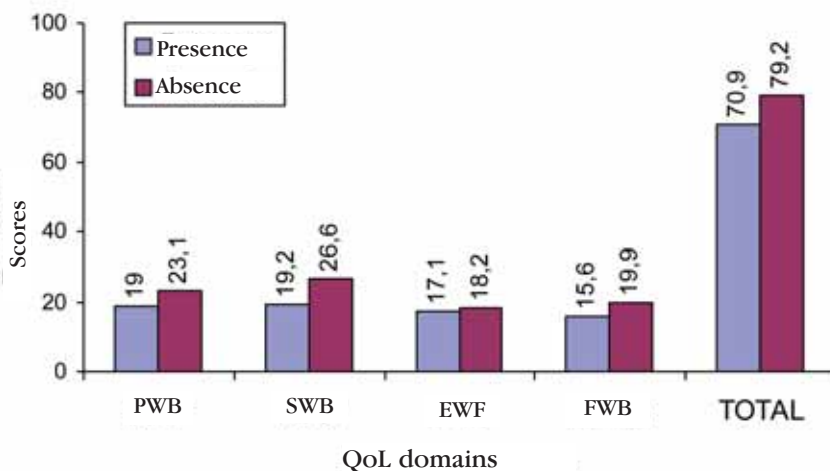
Analysis of the responses to QoL questionnaires allows this type of relationship to be established with greater precision and consequently permits a more satisfactory analysis of the outcome of any given treatment.²⁵

In randomized clinical trials, evaluation of QoL has been added as another dimension to be studied in addition to the efficacy and safety of drugs. Improvements in this dimension have become as important as clinical and laboratory responses to interventions, since in addition to providing information on the impact of the disease, they act as an independent predictor of survival and therapeutic



GRAPH 2: Correlation between scores in the FACT-G quality of life questionnaire and marital status

Physical well-being (PWB); social/family well-being (SWB); emotional well-being (EWB); functional well-being (FWB)



GRAPH 3: Correlation between scores in the FACT-G quality of life questionnaire and the presence or absence of metastases

Physical well-being (PWB); social/family well-being (SWB); emotional well-being (EWF); functional well-being (FWB)

response in patients with cancer.^{26,27}

Evaluation of QoL plays a crucial role in assessing the changes occurring in the patient and their disease during therapy and this comprehension may make treatment more effective.²⁸ Since it includes both subjective and objective criteria, it may enable clinical management guidelines to be developed that would reflect a more accurate picture of the costs and benefits of treatment.²⁸

In a study performed in 2006 with patients with cancer of the head and neck using the FACT-G instrument, scores ranged from 35 to 107, with a median of 86. In the present study, FACT-G scores ranged from 23 to 98, with a mean of 79.2; therefore, patients with melanoma had a lower mean QoL score compared to patients with cancer of the head and neck.²⁹

Reports in the literature regarding QoL in oncology patients show that factors related to the tumor (i.e. stage, site) are not predictive of quality of life and this was also clear in the present study conducted using the FACT-G.^{29,30} In a study on the predictors of quality of life in skin melanoma conducted in Finland, Lehto et al.³⁰ also reported correlations between sociodemographic factors, but not tumor-related factors, and patients' quality of life.

The presence of metastases was only associated with low quality of life scores in the functional well-being domain, showing that the daily routine, professional activities and sleep quality of patients with metastatic melanoma are negatively affected, and their enthusiasm for life is diminished. Some refused to accept the disease and were unsatisfied with their current quality of life.

Although the patients with a family history of skin melanoma were few in the present study (6

cases), there was a statistically significant difference in the overall score when compared with the patients with no family history. The hypothesis could thus be raised that patients with more information and knowledge of the course of the disease would be better prepared to deal with the diagnosis of cancer. Being married was associated with a better quality of life score. This suggests that the presence of a partner may offer greater comfort and emotional support to the patient with a diagnosis of melanoma.

Gender and whether the patient is currently employed were not associated with an alteration in quality of life. A poor education level was associated with poorer QoL as far as pre-established MID was concerned, which corroborates with the possibility that patients with a low socioeconomic level have more difficulty in dealing with the disease.

It is therefore considered necessary to identify the groups of patients with a lower QoL score and create specific protocols to provide differentiated care in these cases and offer support therapy (more frequent consultations, referral for psychological care and even the creation of support groups). In studies in which support therapy was offered to the participants, the authors reported that quality of life and survival improved in the patients who participated in a psycho-educational support group.^{22,26,27}

Evaluation of QoL is crucial in the overall evaluation of patients, both with respect to treatment and follow-up. The development of instruments to evaluate this aspect should be encouraged, not only the translation and validation of existing instruments, but also the elaboration of new instruments specifically designed for different cultures or social groups, since evaluation of quality of life has become an integrated part of patient care.

CONCLUSIONS

In the present study, the following factors were correlated with improved quality of life: being married, having a family history of melanoma and having an education level above primary school level. No dif-

ferences in QoL scores were associated with the characteristics of the skin tumor: Breslow thickness, Clark's level, clinical type or tumor recurrence. □

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