Development and validation of the Nightingale Symptom Assessment Scale (N-SAS) and predictors of the quality of life of the cancer patients in Turkey

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A B S T R A C T

Purpose: Treatment-related side effects have an adverse impact on the health-related quality of life (HRQoL) of cancer patients undergoing chemotherapy. This study is a description of the validity and responsiveness demonstrated by a new cancer and cancer treatment-specific symptom scale – the Nightingale Symptom Assessment Scale (N-SAS) - which was developed and validated to address the QoL of Turkish cancer patients.
Method: The comprehensiveness and clarity of the scale was assessed using 10 patients and pilot testing was carried out with 179 patients. A sample of 374 cancer patients who had received chemotherapy participated in the main study. Descriptive statistics were calculated and comparative tests and factor analysis were performed.
Results: The internal reliability of N-SAS was examined and the validity of this scale was determined by correlation with FACT-G. The scale showed high internal reliability, Cronbach's α for the subscales varied between 0.81 and 0.87 and was 0.93 for the tool. Longitudinal analyses showed that changes in N-SAS scores were strongly correlated with changes in FACT-G. Multivariate analysis revealed that having a metastatic cancer diagnosis, having a low level of income, receiving taxane-based therapy and being a woman were the most important predictive factors for the well-being of the cancer patients in this study.
Conclusions: The high correlation with the FACT-G suggests that the new scale is a valid instrument that can be used to evaluate the effect of antineoplastic therapies on a cancer patient's QoL and can help guide nursing care as well as track the improvement of patients' HRQoL.

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Introduction

Cancer is a major disease burden worldwide and most people perceive it as a frightening and untreatable disease that implies death. Each year, tens of millions of people are diagnosed with cancer around the world, and it is estimated that in 2020, this number will reach 15 million (Turgay et al., 2008; Ma and Yu, 2006). A large proportion of cancers can be cured and more than half of these patients will eventually die of the disease. Depending on the type and stage of disease all patients will be treated with different treatments (Ma and Yu, 2006; WHO, 2007). Chemotherapy is one of the primary treatment methods used in

the treatment of cancer patients. Although advances in chemotherapy have increased in recent years, some regimens can cause many physical and psychological effects that have an adverse impact on the health-related quality of life of cancer patients. Assessment of patients' subjective tolerance of the treatment during and after therapy is important and expected; the positive effects of treatment must be weighed against the negative effects (Turgay et al., 2008).

Health-related quality of life (HRQoL) is a measure used to describe the physical, social, and psychological well-being of an individual and to assess the burden of disease or therapy on daily living (Ganz and Goodwin, 2007). Several general measures of the impact of cancer treatment on HRQoL have been developed by the EORTC [European Organization for Research and Treatment] (Aaronson et al., 1993), CORE [Center on Outcomes, Research and Education] (Cella et al., 1993) and other researchers. Although these QoL instruments are used with all cancer patients in the world, there are clear differences in QoL between cultures. Differences were evident for all different QoL indicators assessed at baseline in

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some scales and also the change over time was not consistent in all cultures (deHaes and Olschewski, 1998; Scott et al., 2008). Some response variations that have the potential to affect the QoL results of international studies were identified, but it was not always clear whether the source of the variation was primarily linguistic or cultural (Scott et al., 2007). A few Turkish-language versions of these QoL instruments are now available for cancer patients in Turkey. Because of the cultural dependence, sometimes it is not possible or feasible to use translated instruments developed in other languages. Cultural adaptation is necessary for a good QoL instrument because of the protective and tolerant attitude toward the disease, a fatalistic mentality, and a cohesive effect of the disease on family members, which are all prevailing characteristics of the Turkish society. A strong correlation between patients' perceived symptoms related to cancer treatment and quality of life has been reported in different studies by using translated measures (Akin et al., 2008; Arslan and Bolukbas, 2003; Beser and Oz, 2003; Ozyilkan et al., 1995; Pinar et al., 2003; Yesilbalkan et al., 2005). However, an instrument with Turkish cultural characteristics is necessary to measure the quality of life of cancer patients in our country and using this scale many factors that affect the QoL of the these cancer patients can be determined.

Published studies describe numerous factors that affect the QoL of cancer patients, and it is difficult to demonstrate the effect of any specific variables (Pinar et al., 2003). While Rabin et al. (2008) explained that no statistical significance was found among the demographic variables, staging, time of disease, chemotherapy and the QoL domains, Engel et al. (2003) stated that age, surgery, marital, educational and employment status were significant predictors associated with the quality of life of cancer patients. Although the physician remains the central figure in the treatment of cancer patients, oncology nurses also play an important role in monitoring the cancer patients' physical symptoms and their levels of physical and psychosocial functioning (Hilarius et al., 2008). Nurses are in contact with patients at all stages of cancer, points in treatment, and care settings, and they have more in-depth, day-to-day contact with the patient than does the medical oncologist, and can be more proactive and innovative in the care efforts intended to maximize the health-related quality of life of patients with cancer (Turgay et al., 2008; Hilarius et al., 2008). HRQoL is one of the most important outcome measures in cancer care and comprehensive evaluation of this issue will provide information that can be used to direct patient care, education, and counseling in order to sustain a person's physical and psychological well-being during and after treatment (Turgay et al., 2008; Pinar, 2004; Rosenbloom et al., 2007; Wan et al., 2008).

The purpose of this study, therefore, was to develop and validate the Nightingale Symptom Assessment Scale (N-SAS), a treatment-specific QoL instrument, to identify the areas of cancer patients' lives most impaired by antineoplastic therapy.

Methods

There were two phases in the development and validation of the Nightingale Symptom Assessment Scale (N-SAS). Phase I focused on instrument construction and included item development, establishment of concurrent validity, and pilot testing. Phase II included the factor analysis and psychometric assessment of the scale.

Phase I: scale construction

Item development

The Nightingale Symptom Assessment Scale (N-SAS) developed by the researchers and contained 68 items that addressed the symptoms frequently reported by patients experiencing chemotherapy. There were three main sources used in the development of items for the scale. The first was the Symptom Recording System in our Oncological Clinic. This analysis was used to generate initial items for the measure. The second source was the definition of the symptoms used by patients during symptom expression. The intent of this step was to create items that would increase the clinical sensitivity of the measure. The third source was the literature and extant instruments that assess the experience of cancer patient during treatment (Aaronson et al., 1993; Cella et al., 1993). This analysis was used to constitute the scoring and factor construction of the items and scale.

Content validity

As part of the item construction and prior to full-scale testing of the measure, content validity was assessed by 10 cancer patients. Each patient was interviewed and asked to comment on the comprehensiveness and clarity of the items and the degree of difficulty encountered in answering the questionnaires.

Pilot testing

The Nightingale Symptom Assessment Scale was pilot tested with a convenience sample of 179 cancer patients (Can, 2008). The purpose of pilot testing is to estimate initial content validity from a relevant population of interest. Respondents were asked to comment on items and offer suggestions for improvement of the instrument. The questionnaire could be completed in 7 to 10 minutes and patients cited that this questionnaire was easy to read and be understood by them. Some phrases were changed according to patients' proposals.

Phase II: factor analysis and psychometric assessment of the scale

Research setting and sample

This study was conducted from January 2008 to February 2009 in the Istanbul University Institute of Oncology, Turkey. The inclusion criteria were age 17 years or older, competency in written and spoken Turkish, and the ability to consent to participate in the study. If the patient had received first chemotherapy, had a social or psychological state that would interfere with their participation in the study, or if they did not want to participate in the study after it was explained to them, they were not included in the study. According to the inclusion criteria a sample of 374 cancer patients who had received chemotherapy participated in the study. Informed consent was obtained in accordance with the Istanbul University Ethics Review Board.

Data collection

Before treatment was begun a Patient Characteristics Form was used in the assessment of patients' personal and illness-related characteristics, the Nightingale Symptom Assessment Scale (N-SAS) was used in the determination of treatment-related side effects, and the Functional Assessment of Cancer Therapy Scale – General (FACT-G) was used in the evaluation of the quality of life of patients who were participating in the study. Patients who were well enough completed the questionnaires themselves; for those who were too weak to do so, a friend or relative was asked to assist by verbally presenting the questions to the patient and completing the forms according to the patient's responses.

The Patient Characteristics Form developed by the researchers contained 28 items that addressed the usual demographic data (e.g., age, income level, employment status) and disease and

treatment characteristics (e.g., surgical therapy, radiation therapy, chemotherapy).

The Nightingale Symptom Assessment Scale (N-SAS) developed by the researchers was dependent on the symptom intensity and definition of the symptoms used by the cancer patients during assessment of the treatment-related symptoms. This Likert-type QoL scale included 68 symptoms frequently reported by cancer patients. The severity of symptoms experienced by the patients was quantified using five possible numeric responses, where 0 = not at all, 1 = a little bit, 2 = somewhat, 3 = quite a bit and 4 = very much.

The Functional Assessment of Cancer Therapy – General (FACT-G) is a validated, cancer-specific quality-of-life instrument designed to identify areas of concern for cancer patients during the previous seven days. It consists of four core domains (physical, social/family, emotional, and functional) (Cella et al., 1993). The format of items in the FACT-G measure, consisting of five possible numeric responses, where 0 = not at all, 1 = a little bit, 2 = somewhat, 3 = quite a bit, and 4 = very much. The FACT-G is scored by summing the 4 subscales to yield a composite quality of life score for each person; higher scores indicate better quality of life.

Ethical considerations

The study was approved by the administration of the Istanbul University Oncology Institute. The patients were informed about the nature of the study and verbal consent was obtained.

Data analyses

The SPSS 16.0 (SPSS Inc.) program was used for data analysis. Descriptive statistics, means, medians, frequencies, and percentages were used to show the distribution of the personal characteristics, illness-related characteristics, and quality of life. Factor analysis was performed. The internal reliability was examined with Cronbach's α, and validity was determined by Spearman's

correlation test with a previously validated tool measuring quality of life. The Mann–Whitney U, Kruskal–Wallis, and Spearman's correlation tests were also used in the assessment of factors affecting the treatment-related QoL of the cancer patients. Logistic regression analysis was used to predict the factors affecting the treatment-related symptom experience of the cancer patients, where patients' symptom experience between 0 and 1 were accepted as "0" = No symptoms and between 2 and 4 as "1" = "Had symptoms". For all statistical analyses, a two-sided p value of less than 0.05 was considered to be statistically significant.

Results

Patients' demographic and clinical characteristics

The patients' mean age was 50.09 ± 16.75 (range 17–85), 55.1% ($n = 206$) were female, 80.2% ($n = 300$) were married and 47.3% ($n = 177$) were primary school graduates. Most of the patients ($n = 276$) were housewives or retired and 10.4% ($n = 39$) reported that their income level is low. Almost all of the patients (94.9%) had health insurance (Table 1).

The median length of time since being given the diagnosis of cancer was seven months ($\bar{x} = 16.75 \pm 24.56$, range 1–180 months) and the median treatment cycle was 4 ($\bar{x} = 5.52 \pm 4.71$, Range 1–24). Most of the patients had breast (25.7%), colo rectal

Table 1
Patients' demographic characteristics ($N = 374$).

	n	%
Gender		
Women	206	55.1
Men	168	44.9
Marital status		
Married	300	80.2
Single	74	19.8
Education		
Primary school	177	47.3
Middle school	63	16.8
High school	85	22.7
University	49	13.1
Occupation		
Housewife	153	40.9
Retired	123	32.9
Student	9	2.4
Employed	89	23.9
Income level		
Low	39	10.4
Good	335	89.6
Employment status		
Employed	63	16.8
Not employed	311	83.2
Health insurance		
Uninsured	19	5.1
Insured	355	94.9

Table 2
Patients' disease and treatment-related characteristics ($N = 374$).

	n	%
Diagnosis		
Breast cancer	94	25.7
Colo-rectal cancer	66	18.0
Lung cancer	53	14.5
Gastric cancer	25	6.8
Skin and soft tissue cancer	10	2.7
Gynecological Cancer	42	11.5
Lymphoma	23	6.3
Bone cancers	15	4.1
Head and Neck Cancer	16	4.4
Urological cancer	22	6.0
Location of disease		
Primary disease	208	62.7
Metastatic disease	124	37.3
ECOG[a] performance status		
0 = Fully active, able to carry on all pre-disease performance without restriction	181	53.9
1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work	106	31.5
2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours	49	14.6
Surgical therapy		
Yes	232	63.4
No	134	36.6
Radiation therapy		
Yes	138	38.8
No	218	61.2
Chemotherapy		
Platinum-based therapy	117	39.9
Fluorouracil-based therapy	40	13.7
Taxane-based therapy	51	17.4
Doxorubicin-based therapy	32	10.9
Targeted therapy	26	8.9
Other chemo regimens	27	9.2

[a] ECOG – Eastern Cooperative Oncology Group.

(18%), and lung (14.5%) cancer diagnoses. Two hundred and eight of the patients (62.7%) had primary disease, 53.9% had an EGOC score of 0, 63.4% had undergone surgical therapy and 38.8% had undergone radiation therapy. The patients' chemotherapy included platinum-based therapy for 39.9% ($n = 117$), taxane-based therapy for 17.4% ($n = 51$), and fluorouracil-based therapy for 13.7% ($n = 40$) (Table 2).

Factor analysis

The factor analysis for the N-SAS draft tool was carried out by a principal component analysis with varimax rotation and the acceptable level for scale items was set to be above 0.40. At the first iteration, items with a factor loading of <0.40 were excluded. The factor extraction was then limited to four factors based on the observed factor structures seen in previous studies (Ganz and Goodwin, 2007; Cella et al., 1993). The algorithm for the factor analysis is detailed in Fig. 1. Based on this algorithm the factor analysis was run four times before it met the selection criteria. The four-factor structure resulted in a total of 38 items (Appendix I) that constitute the subgroup of the scale: Psychological Well-being (PsWB) (factor 1 = 10 items), Social Well-being (SoWB) (factor 2 = 8 items), Sensorial Well-being (SeWB) (factor 3 = 5 items), and Physical Well-being (PhWB) (factor 4 = 15 items). Because the sensorial and physical symptoms reflect the physical well-being of the cancer patients, in this study factor 3 and factor 4 were

combined under the Physical Well-being subgroup. Eigen values were 28.26, 6.38, 5.07, and 4.21, respectively (Table 3). Kaiser–Meyer–Olkin measure of sampling adequacy was 0.89.

Internal consistency: Cronbach's Alpha

The internal consistency of the N-SAS was assessed using item-total score correlations and Cronbach's alpha reliability coefficient. To obtain the subgroup scores, the scores for each item were added for each subgroup and divided by the number of items in the subgroup. The total N-SAS score is obtained by adding the scores for all the items and dividing by the total number of items. The acceptable value for the scale internal consistency was set at 0.70. Test–retest reliability could not be evaluated because of rapid changes in the patients' health status occurring as a result of the chemotherapy. This made it impossible to tease out whether a systematic shift in scores occurred over time.

The statistical analysis revealed that item-total correlations were high and the Cronbach alpha reliability coefficients were good for the subscales and for the overall scale (Table 3).

Concurrent validity: N-SAS and FACT-G

Concurrent validity was determined by examining the degree of correlation between N-SAS and the previously validated
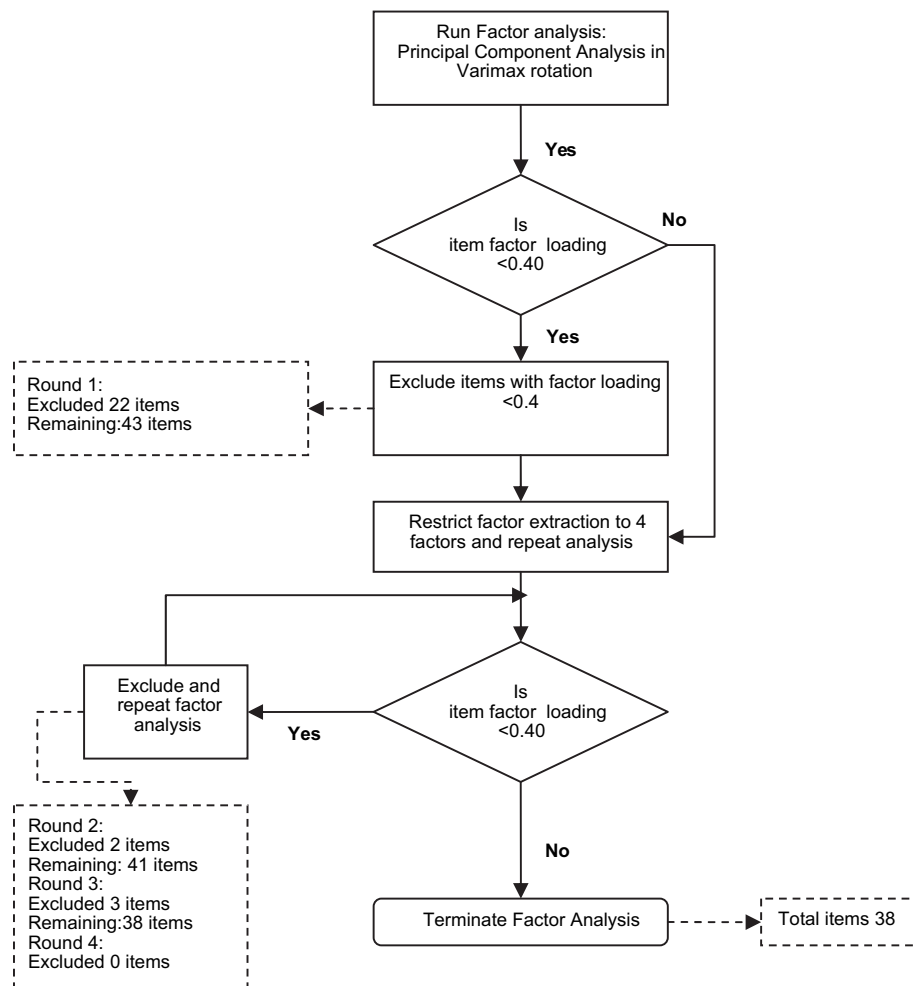

Fig. 1. Algorithm for the factor analysis.

Table 3
The Nightingale Symptom Assessment Scale (N-SAS) – rotated factor matrix and internal consistency ($N = 374$).

	Factor loading	Subgroup scores		Total scale score	
		r_S	p	r_S	P
Psychological Well-being (PsWB)					
I had difficulties meeting my daily needs.	0.79	0.74	0.0001	0.61	0.0001
I had difficulties continuing my daily activities.	0.74	0.73	0.0001	0.65	0.0001
My relationship with my family and friends was disturbed.	0.59	0.59	0.0001	0.52	0.0001
I avoided having contact socially.	0.68	0.68	0.0001	0.60	0.0001
I got angry quickly.	0.60	0.74	0.0001	0.64	0.0001
I felt fury and anger.	0.65	0.76	0.0001	0.66	0.0001
I felt myself withdraw.	0.61	0.67	0.0001	0.59	0.0001
I had worries about the future.	0.61	0.69	0.0001	0.62	0.0001
I was under strain going for a walk.	0.60	0.71	0.0001	0.64	0.0001
My interest in sexual intercourse was decreased.	0.60	0.57	0.0001	0.47	0.0001
Cronbach's Alpha /Based on Standardized Items		0.87			
Social Well-being (SoWB)					
My forgetfulness increased.	0.43	0.61	0.0001	0.56	0.0001
I had alopecia.	0.58	0.74	0.0001	0.54	0.0001
My eyebrow and eyelashes fell out.	0.71	0.74	0.0001	0.55	0.0001
I had dryness and exfoliation on my skin.	0.59	0.61	0.0001	0.53	0.0001
I had redness on my palms and soles.	0.67	0.55	0.0001	0.48	0.0001
My nails changed.	0.73	0.63	0.0001	0.49	0.0001
My skin color became darker.	0.61	0.60	0.0001	0.57	0.0001
I had itching.	0.58	0.49	0.0001	0.39	0.0001
Cronbach's Alpha /Based on Standardized Items		0.81			
Physical Well-being (PhWB)					
I felt tired.	0.52	0.65	0.0001	0.55	0.0001
I did not want to go out.	0.47	0.59	0.0001	0.55	0.0001
My sleeping pattern was disturbed.	0.40	0.54	0.0001	0.47	0.0001
I was forced to concentrate.	0.48	0.56	0.0001	0.55	0.0001
My mouth or gums were sensitive.	0.44	0.66	0.0001	0.60	0.0001
My mouth was injured.	0.54	0.62	0.0001	0.53	0.0001
I had a sore throat.	0.56	0.57	0.0001	0.46	0.0001
I could hardly swallow food.	0.53	0.56	0.0001	0.47	0.0001
I tasted foods differently.	0.43	0.54	0.0001	0.51	0.0001
My appetite was decreased.	0.52	0.50	0.0001	0.41	0.0001
I had nausea.	0.71	0.58	0.0001	0.47	0.0001
I had vomiting.	0.72	0.44	0.0001	0.33	0.0001
I had constipation.	0.41	0.45	0.0001	0.37	0.0001
I had diarrhea.	0.40	0.30	0.0001	0.31	0.0001
I had fever.	0.64	0.32	0.0001	0.27	0.0001
I had chills.	0.69	0.47	0.0001	0.39	0.0001
I suffered from attacks of hiccups.	0.41	0.24	0.0001	0.20	0.0001
I had numbness or tingling in my hands and feet.	0.49	0.56	0.0001	0.52	0.0001
I had joint or muscle pain.	0.51	0.53	0.0001	0.48	0.0001
I suffered from complaints such as flu.	0.40	0.41	0.0001	0.44	0.0001
Cronbach's Alpha /Based on Standardized Items		0.87		0.93	

r_S – Spearman correlation.

instrument FACT-G using Spearman's correlation coefficients. The level of significance was set at $p < 0.05$ (two-tailed).

Except for Social/Family Well-being (SWB), high correlations were found between the two scales. However, the strong correlations of 0.60 and above were observed between related subgroups on the two scales with regard to Psychological and Physical Well-being and the overall patient QoL scores (Table 4).

Treatment-related QoL of the cancer patients

The subgroup scores and total score of the N-SAS are used as an index of treatment-related well-being, with a higher score indicating worse symptom experience and poor well-being. The range of the scores between 0 and 0.50 indicates very good well-being, 0.51–1.50 good well-being, 1.51–2.50 fair well-being, 2.51–3.50 poor well-being and 3.51–4.00 very poor well-being.

Table 4
The Correlations Between The N-SAS and FACT-G ($N = 374$).

| N-SAS FACT-G	Psychological Well-being (PsWB)		Social Well-being (SoWB)		Physical Well-being (PhWB)		N-SAS total score	
	r_S	p	r_S	p	r_S	p	r_S	p
Physical Well-being (PWB)	−0.77	0.0001	−0.51	0.0001	**−0.74**	**0.0001**	**−0.80**	**0.0001**
Social/Family Well-being (SWB)	0.05	0.44	**0.16**	**0.03**	0.20	0.008	**0.16**	**0.03**
Emotional Well-being (EWB)	**−0.65**	**0.0001**	−0.37	0.0001	−0.48	0.0001	**−0.60**	**0.0001**
Functional Well-being (FWB)	−0.37	0.0001	−0.08	0.24	−0.27	0.0001	**−0.30**	**0.0001**
FACT-G total score	**−0.65**	**0.0001**	**−0.32**	**0.0001**	**−0.50**	**0.0001**	**−0.59**	**0.0001**

r_S – Spearman correlation.
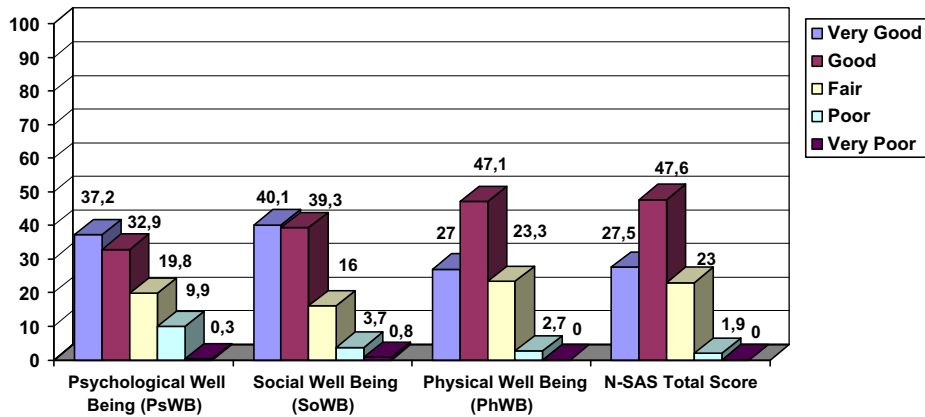
Fig. 2. Treatment-related well-being of the cancer patient, % ($n = 374$).

According to the results of this study, the general well-being of cancer patients was good ($\overline{x} = 1.02 \pm 0.66$) and treatment usually affected the psychological ($\overline{x} = 1.09 \pm 0.91$) and physical ($\overline{x} = 1.05 \pm 0.67$) well-being of the cancer patients. Social well-being was slightly affected ($\overline{x} = 0.92 \pm 0.80$). Therapy-related side effects were not intense and the psychological and physical complaints were those most frequently experienced by the cancer patients (Fig. 2).

Factors affecting the cancer patients' quality of life

The effects of demographic and disease-related characteristics on the treatment-related well-being were evaluated. The statistical analysis revealed that age, gender, marital status, occupation, income level, employment status, and health insurance were the important demographic variables; and diagnosis, location of disease, EGOC performance score, surgical therapy, chemotherapy regimen, chemotherapy cycle, and length of the time since diagnosis were the significant disease-related variables that affected patients' treatment-related well-being.

In this study, the psychological, social, and physical well-being of the female patients, the patients with metastases, and the patients who had undergone surgical therapy were low in comparison to those of retired patients who were housewives ($p < 0.05$). However, in patients who had low level income psychological well-being ($z_{MWU} = -2.09$, $p = 0.03$); in patients with breast and gynecologic cancers diagnosis ($\chi^2_{KW} = 45.62$, $p = 0.0001$) and who had received taxan based therapy ($\chi^2_{KW} = 23.83$, $p = 0.0001$) social well-being; and in single patients ($z_{MWU} = -1.99$, $p = 0.04$), students ($\chi^2_{KW} = 21.28$, $p = 0.0001$), and who had bone or gynecologic cancers diagnosis ($\chi^2_{KW} = 24.14$, $p = 0.004$) physical well-being was low.

All problems related to therapy were more prevalent, especially in female patients ($z_{MWU} = -5.34$, $p = 0.0001$), in patients who had low-level income ($z_{MWU} = -2.31$, $p = 0.02$), in patients who had metastatic disease ($z_{MWU} = -4.309$, $p = 0.0001$), in patients who had undergone surgical therapy ($z_{MWU} = -3.06$, $p = 0.002$), in patients who were unemployed ($z_{MWU} = -2.04$, $p = 0.04$), in comparison to retired patients who were housewives ($\chi^2_{KW} = 23.64$, $p = 0.0001$), who had breast, gynecological or bone cancer diagnoses ($\chi^2_{KW} = 29.69$, $p = 0.0001$), and who had received taxane-based therapy ($\chi^2_{KW} = 16.40$, $p = 0.006$).

Furthermore, it was determined that the psychological, social, physical, and general well-being increased with age and decreased with an increased ECOG performance score and a prolonged length of time since diagnosis or starting treatment, except for the relationship between psychological well-being and the treatment cycle (Table 5).

Logistic regression analysis of the factors affecting patients' treatment-related QoL

Depending on the factors affecting psychological (gender, income level, location of disease, surgical therapy, and occupation); social (gender, location of disease, surgical therapy, occupation, type of diagnosis, and treatment); physical (gender, marital status, employment status, location of disease, surgical therapy, occupation, and type of diagnosis); and overall (gender, income level, employment status, location of disease, surgical therapy, occupation, and type of the diagnosis and treatment) well-being found by the univariate analysis results, four logistic regression models were constituted.

Logistic regression analysis revealed that the predictive factors for the psychological well-being were having a metastatic cancer diagnosis and being a woman; for social well-being they were being a woman, undergoing taxane therapy, and having a metastatic disease; for physical well-being they were having surgery, having a metastatic disease, and being a woman; and for overall

Table 5
The relationship between treatment-related well-being and age, ECOG performance score, length of the time since diagnosis or the start of treatment ($N = 374$).

	Age ($n = 352$)		ECOG ($n = 336$)		Diagnosis time ($n = 349$)		Treatment cycle ($n = 115$)	
	r_s	p	r_s	p	r_s	p	r_s	p
Psychological Well-being (PsWB)	−0.14	0.005	0.37	0.0001	0.20	0.0001	0.15	0.09
Social Well-being (SoWB)	−0.21	0.0001	0.15	0.005	0.27	0.0001	0.36	0.0001
Physical Well-being (PhWB)	−0.14	0.006	0.27	0.000	0.20	0.0001	0.26	0.004
N-SAS Total Score	−0.18	0.001	0.32	0.0001	0.27	0.0001	0.30	0.001

r_s – Spearman correlation.

Table 6
The logistic regression analysis of variables that are significantly associated with patients' experience of symptoms ($N = 374$).

Step		B	S.E.	df	Sig.	Exp(B)	95% CI for EXP(B)	
							Lower	Upper
	Psychological Well-being							
1	Primary (reference)					1		
	Metastatic	**0.86**	**0.25**	**1**	**0.001**	**2.37**	**1.44**	**3.89**
2	Males (reference)					1		
	Females	**0.71**	**0.26**	**1**	**0.006**	**2.03**	**1.22**	**3.39**
	Social Well-being							
1	Males (reference)					1		
	Females	**1.42**	**0.43**	**1**	**0.001**	**4.16**	**1.76**	**9.84**
2	Taxane-based therapy (reference)					1		
	Platinum-based therapy	−0.06	0.56	1	0.91	0.94	0.31	2.85
	Fluorouracil-based therapy	0.01	0.65	1	0.98	1.01	0.28	3.62
	Doxorubicin-based therapy	−0.76	0.48	1	0.11	0.46	0.17	1.20
	Targeted therapy	**−2.16**	**1.08**	**1**	**0.04**	**0.11**	**0.01**	**0.95**
3	Primary (reference)					1		
	Metastatic	**0.76**	**0.36**	**1**	**0.03**	**2.15**	**1.05**	**4.393**
	Physical Well-being							
1	No surgical therapy (reference)					1		
	Had surgical therapy	**0.83**	**0.30**	**1**	**0.006**	**2.29**	**1.26**	**4.16**
2	Primary (reference)					1		
	Metastatic	**0.75**	**0.26**	**1**	**0.005**	**2.13**	**1.26**	**3.61**
3	Males (reference)					1		
	Females	**0.64**	**0.28**	**1**	**0.022**	**1.90**	**1.09**	**3.31**
	N-SAS							
1	Taxane-based therapy (reference)					1		
	Platinum-based therapy	−1.08	0.57	1	0.06	0.33	0.11	1.03
	Fluorouracil-based therapy	−0.92	0.66	1	0.16	0.39	0.10	1.46
	Doxorubicin-based therapy	**−0.99**	**0.43**	**1**	**0.02**	**0.36**	**0.15**	**0.86**
	Targeted therapy	**−2.90**	**1.07**	**1**	**0.007**	**0.05**	**0.007**	**0.44**
2	Males (reference)					1		
	Females	**1.11**	**0.38**	**1**	**0.004**	**3.046**	**1.437**	**6.456**
3	Good income level (reference)					1		
	Low income level	**1.34**	**0.57**	**1**	**0.02**	**3.824**	**1.240**	**11.797**
4	Primary (reference)					1		
	Metastatic	**0.69**	**0.34**	**1**	**0.04**	**2.013**	**1.034**	**3.916**

well-being they were undergoing taxane-based therapy, being a woman, having a low level of income, and having metastatic disease (Table 6).

Discussion and conclusion

Many HRQoL instruments for cancer patients have been developed (Ganz and Goodwin, 2007; Aaronson et al., 1993; Cella et al., 1993). While these instruments offer many options for HRQoL, sometimes it is difficult to select an appropriate one for a specific aim or it is not possible/feasible to use translated instruments developed in other languages because of the cultural dependence. Cultural adaptation is necessary for a good QOL instrument because of a protective and tolerant attitude toward the disease, a fatalistic mentality, and the cohesive effect of the disease on family members, which are all prevailing characteristics of Turkish society. The first aim of this study was to develop and validate a treatment-specific QoL instrument for cancer patients whose quality of life has been impaired by antineoplastic therapy. Based on the observed factor structures seen in previous studies (Ganz and Goodwin, 2007; Cella et al., 1993), the factor extraction was limited to four factors, but the structure of the scale resulted in three subgroups reflecting the physical, social, and psychological well-being of an individual in order to assess the burden of disease or therapy on daily living as described in the HRQOL definition by Ganz and Goodwin (2007). The statistical analysis revealed that the N-SAS showed high internal reliability

and good convergent and discriminant validity when correlated with FACT-G. This scale can therefore be used to evaluate the effect of antineoplastic therapies on a cancer patient's QoL and can help guide nursing care as well as track the improvement in patients' QoL (Turgay et al., 2008; Hilarius et al., 2008). Because the items' content assessing the social well-being of the cancer patients was different on the two scales, correlation was low for this subgroup. However, the items in the N-SAS social well-being subgroup were strongly correlated with changes in their own subgroup and overall scale scores and Cronbach's α values were acceptable for both. The high correlations and acceptable Cronbach's α values suggested that the social well-being subgroup can be used to monitor the level of impairment of the social well-being of cancer patients suffering because of their therapy. The N-SAS has some advantages over the currently widely used EORTC QLQ-30 (Aaronson et al., 1993) and FACT-G (Cella et al., 1993). There are too many variables to analyze in EORTC QLQ-C30. It includes five functional subscales, three symptom subscales, an overall health status subscale, and six single items. Its hierarchical structure is not so clear. It does not calculate the overall score (Wan et al., 2008). The FACT-G can only calculate the scores of four domains and the overall score in which the social well-being questions are not very appropriate for our culture because of the close concern, support, and help of the spouse, friends, relatives, patients, and environment. However, the N-SAS was developed in accordance with the experience of Turkish cancer patients and represents their cultural characteristics.

The second aim of this study was to identify the areas of the cancer patient's life most impaired by antineoplastic therapy, using the newly developed scale. Although the treatment-related side effects were not intense in the cancer patients in this study, all types of treatment-related symptoms were most prevalent, especially in women, in patients who were housewives and who had metastatic disease or surgical therapy, and the well-being of these patients was poor. These results were in accordance with those of Turgay et al. (2008) and Ogce et al. (2007) who found that QoL was low in women and housewives (Turgay et al., 2008) and an increase in cancer stage triggers a decrease in psychological and overall quality of life in cancer patients (Ogce et al., 2007). On the other hand, while Guner et al. (2006) reported that the QoL was low for men; Pinar et al. (2003) cited that QoL scores were not different according to the gender of the patients, the presence of metastasis, and the type of the cancer treatment.

However, psychological well-being was lowest in patients who had a low level-income, social well-being was lowest in patients who had breast or gynecological cancer diagnoses and who had received taxane-based therapy, and physical well-being was lowest in single patients, patients who were students, and patients who had bone or gynecological cancer diagnoses. Similar to the results in this study, Guner et al. (2006) also found that patients who were widowed or housewives, and who had low income experienced a greater decrease in QoL in comparison to other groups. Ogce et al. (2007) reported that lower income negatively affected the overall quality of life and working at a job decreased the psychological stressors in patients. In contrast to the present study, Pinar et al. (2003) did not find a relationship between the QoL scores and the financial or marital status of the patients. At the same time, in other studies it was stated that the QoL was high in single patients (Turgay et al., 2008), and although the result is not significant, patients with lung cancer had the lowest QoL scores in the whole group (Pinar et al., 2003). Nearly half of the patients need financial and psychological help during treatment (Gozum and Akcay, 2005) and in Turkey, patients prefer family members to be their caregivers rather than friends or neighbors (Bektas and Akdemir, 2008). Therefore, great social support increased the coping strategies and reduced the feelings of hopelessness of the cancer patients (Tan and Karabulutlu, 2005; Tan, 2007). However, single patients are unable to receive support from their families, as married ones do, and must take care of their needs themselves.

Furthermore, in the current study the negative correlations were found between the age and well-being of the cancer patients. It was determined that the psychological, social, physical, and general well-being was better in the older patients. This result was not supported by other studies, which found that older age was associated with poorer psychological and physical well-being, symptom management, and overall QoL (Pinar et al., 2003; Ogce et al., 2007; Guner et al., 2006). As can be seen from the various results in the literature, the relationship between age and QoL is not consistent. According to the literature, older adults are better able to cope with crises as a result of their life experiences, so that when cancer is diagnosed, they are less prone to displaying negative psychosocial reactions (Guner et al., 2006). At the same time, the elderly patients were not treated using aggressive therapy regimens.

A high ECOG performance score and prolonged length of time since diagnosis or start of treatment decreased the psychological, social, physical, and general well-being of the patients, except for psychological well-being during a treatment cycle. Similar to the current study Pinar et al. (2003) found a negative, nonsignificant correlation between duration of cancer and psychological well-being and overall QOL. The reason for that is because these patient subgroups were usually metastatic cancer patients who had additional problems related to the disease process requiring medical support.

In various studies it has been reported that the education level is an important variable in the well-being of cancer patients (Turgay et al., 2008; Pinar et al., 2003). In this study, no effect of education level, health insurance, and radiation therapy on the well-being of cancer patients was detected.

Multivariate analysis revealed that having a metastatic cancer diagnosis and being a woman were the predictive factors for poor psychological, social, and physical well-being in cancer patients. However, additional predictive factors for poor social and physical well-being were undergoing taxane-based therapy and undergoing surgery, respectively. At the same time, it was determined that undergoing taxane-based therapy, a low level of income, a metastatic cancer diagnosis or being a woman were the predictive factors for the overall poor well-being of the cancer patients during antineoplastic therapy. To our knowledge, there are few studies showing the predictive factors of the quality of life of cancer patients. One of these studies was the cross-sectional study carried out by Rabin et al. (2008) in which demographic and clinical factors that interfere with the quality of life of breast cancer patients were investigated. Hierarchical multiple linear regression analyses were performed on all variables, with no statistical significance found among the demographic variables, staging, duration of disease, chemotherapy, and the QoL domains. Nevertheless, patients who underwent mastectomy indicated lower QoL scores in the physical ($p < 0.002$) and psychological ($p < 0.02$) domains. On the other hand, Engel et al. (2003) reported that age, surgery, marital, educational, and employment status was significant predictors associated with the quality of life of the cancer patients. Because only surgical therapy was found to be the common predictive factor, more studies need to be carried out in this area.

Implications for practice

The statistical analysis revealed that the N-SAS can be used to evaluate the effect of antineoplastic therapies on a cancer patient's QoL and can help guide nursing care as well as track the improvement of the patient's QoL. Having a metastatic cancer diagnosis, having a low level of income, undergoing taxane-based therapy, and being a woman were the most important predictive factors in the well-being of the cancer patients in this study. These results are vital for healthcare providers needing to focus on designing psychosocial interventions to improve self-care and quality of life, and for supporting cancer patients throughout their illness and therapy, not only in our country, but all over the world.

Limitations

The limitations of this study might be mixing patients at different stages and undergoing different chemotherapy treatments. In further studies, the patients' stages and treatment characteristics need to be specified to be able to obtain more information about the relationship between quality of life and patients' characteristics.

Conflict of interest

The study was not supported financially by any organization or people.

Appendix I. Turkish version of the Nightingale Symptom Assessment Scale (N-SAS)

Nightingale Semptom Değerlendirme Ölçeği

Aldığınız tedavi farklı sorunlar yaşamamıza neden olabilir. Bu nedenle aşağıda yer alan ifadeleri dikkatlice okuyarak tedavi sonrası yaşadığınız sorunların yoğunluğunu size en yakın cevabı seçerek işaretleyiniz. Okuduğunuz sorunu yaşamadıysanız "Hayır" cevabını seçiniz.

	Hayır	Çok az	Biraz	Oldukça	Çok fazla
1. Kendimi yorgun hissettim	0	1	2	3	4
2. Dışarıya çıkmak istemedim	0	1	2	3	4
3. Uyku düzenim bozuldu	0	1	2	3	4
4. Dikkatimi yoğunlaştırmakta zorlandım	0	1	2	3	4
5. Unutkanlığım arttı	0	1	2	3	4
6. Ağzımda/dişetlerimde hassasiyet oldu	0	1	2	3	4
7. Ağzımda yara oldu	0	1	2	3	4
8. Boğazımda ağrı oldu	0	1	2	3	4
9. Lokmaları yutmakta zorlandım	0	1	2	3	4
10. Yediklerimin tadını farklı algıladım	0	1	2	3	4
11. İştahım azaldı	0	1	2	3	4
12. Bulantım oldu	0	1	2	3	4
13. Kusmam oldu	0	1	2	3	4
14. Kabız oldum	0	1	2	3	4
15. İshal oldum	0	1	2	3	4
16. Saçlarım döküldü	0	1	2	3	4
17. Kirpiklerim ve kaşlarım döküldü	0	1	2	3	4
18. Cildimde kuruluk arttı/pul pul döküntüler oldu	0	1	2	3	4
19. Avuçlarımda ve ayak tabanlarımda kızarıklık oldu	0	1	2	3	4
20. Tırnaklarımın görünümü/yapısı değişti	0	1	2	3	4
21. Cilt rengim koyulaştı	0	1	2	3	4
22. Kaşıntım oldu	0	1	2	3	4
23. Ateşim 38 °C üstüne çıktı	0	1	2	3	4
24. Titremem oldu	0	1	2	3	4
25. Hıçkırığım oldu	0	1	2	3	4
26. El ve ayaklarımda uyuşma/karıncalanma oldu	0	1	2	3	4
27. Eklem /kaslarımda ağrı oldu	0	1	2	3	4
28. Günlük ihtiyaçlarımı karşılamada zorlandım	0	1	2	3	4
29. Günlük işlerimi sürdürmede zorlandım	0	1	2	3	4
30. Aile /arkadaş ilişkilerim bozuldu	0	1	2	3	4
31. Sosyal yaşamdan uzaklaştım	0	1	2	3	4
32. Daha çabuk sinirlenir oldum	0	1	2	3	4
33. Daha duyarlı /hassas oldum	0	1	2	3	4
34. Kendimi içime kapanmış hissettim	0	1	2	3	4
35. Geleceğe yönelik endişelerim oldu	0	1	2	3	4
36. Dışarıda yürüyüş yapmada zorlandım	0	1	2	3	4
37. Grip benzeri şikâyetlerim oldu	0	1	2	3	4
38. Cinselliğe ilgim azaldı	0	1	2	3	4

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