Published in final edited form as:
Gynecol Oncol. 2013 August ; 130(2): 323–328. doi:10.1016/j.ygyno.2013.05.009.

Validating the M. D. Anderson Symptom Inventory (MDASI) for use in patients with ovarian cancer

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Abstract

Objective—The M. D. Anderson Symptom Inventory (MDASI) captures the severity of common cancer symptoms from the patients' perspective. We describe the validity and sensitivity of a module of the MDASI to be used with patients having ovarian cancer (MDASI-OC).

Methods—Ovarian cancer–specific module items were developed from 14 qualitative patient interviews. 128 patients with invasive epithelial ovarian, peritoneal, or fallopian-tube cancer treated at MD Anderson Cancer Center were recruited. Patients completed the MDASI-OC, socio-demographic questionnaires, the Functional Assessment of Cancer Therapy-Ovary (FACT-O), and a global quality-of-life (QOL) item. Reliability was assessed using Cronbach α and sensitivity using known group was assessed. Construct validity was tested using exploratory factor analysis.

Results—The sample was primarily white (85.2%), had a mean age of 57.5 years (±12.7 years), and had previously been treated with chemotherapy (75.0%) and/or surgery (93.8%). Approximately 30% of patients reported disturbed sleep, fatigue, or numbness/tingling of at least moderate severity (≥5 on a 0–10 scale). On the ovarian-cancer-specific symptoms, approximately 20% reported back pain, feeling bloated, or constipation of at least moderate severity. Factor analysis revealed six underlying constructs (pain/sleep; cognitive; disease-related and numbness; treatment-related; affective; gastrointestinal-specific). MDASI-OC symptom and interference items had Cronbach α values of 0.90 and 0.89, respectively. The MDASI-OC was sensitive to

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Conflict of Interest Statement

Diane C. Bodurka was a consultant for Genentech until December 31, 2012.

symptom severity by performance status (p=0.009), QOL (p=0.002), and FACT-O scores (p<0.001).

Conclusions—The 27-item MDASI-OC meets common criteria for validation and reliability and is sensitive to expected changes in symptoms related to differences in disease and treatment status.

Keywords

Ovarian cancer; MDASI; M. D. Anderson Symptom Inventory; Symptoms; Assessment; Validation

Background

In 2012, an estimated 22,280 new cases of ovarian cancer, the deadliest and second-most-prevalent of the gynecological cancers, were expected [1]. Patients with ovarian cancer frequently report back pain, fatigue, bloating, constipation, abdominal pain, and urinary symptoms [2]; decreasing this symptom burden would vastly improve their quality of life (QOL) and daily functioning. Ovarian cancer is traditionally treated with surgery, chemotherapy, or a combination of these modalities, and it is vital that assessment tools be available to correctly measure the symptoms produced not only by the disease, but also by the treatment. Accurate symptom assessment enables patients and clinicians to make informed decisions about treatment options on the basis of treatment toxicity profiles.

Despite the tremendous impact that symptoms can have on QOL and daily functioning, symptoms are often undertreated because patient report of symptom severity is rarely part of routine cancer care, and validated symptom assessment tools are not readily available to clinicians [3, 4]. Although various instruments have been developed for use in patients with ovarian cancer, including the widely used European Organisation for the Research and Treatment in Cancer Quality of Life Questionnaire – Ovarian Cancer Module (EORTC QLQ-OV28) [5, 6], the Functional Assessment of Cancer Therapy-Ovary (FACT-O) [7], and the recent National Comprehensive Cancer Network – Functional Assessment of Cancer Therapy – Ovarian Symptom Index (NFOSI-18) [8], these questionnaires primarily address the issue of health-related QOL and do not adequately provide a summation of symptom burden described by patients—a metric that is compliant with U.S. Food and Drug Administration (FDA) guidance on the use of patient-reported outcomes to support labeling claims [9].

Because patients are unlikely to complete lengthy, complex forms on a repeated basis, multisymptom questionnaires should be kept straightforward, simple, and as brief as possible. The M. D. Anderson Symptom Inventory (MDASI) is a brief, patient-reported outcome measure of the impact and severity of 13 cancer-related symptoms that are common across all cancer types [10]. The MDASI also measures how much symptoms interfere with daily living. The MDASI is easily understood because of its intuitive 0–10 scale, is translatable into multiple languages because of its simple wording, and can be administered through various media (paper, computer, or telephone) [11].

The MDASI can also be augmented with additional symptom items specific to a particular cancer type. Such MDASI “modules” have already been developed such as brain tumor [12], head and neck cancer [13], treatment-related heart failure [14], thyroid cancer [15], gastrointestinal cancer [16], and lung cancer [17]. Here we report on the development and validation of a MDASI ovarian-cancer module (MDASI-OC) to be used in the assessment of cancer-related and treatment-related symptoms in patients with ovarian cancer.

Methods

Participants

Patients were recruited from the ambulatory clinics in the gynecology centers and inpatient gynecology units at The University of Texas MD Anderson Cancer Center and Lyndon B. Johnson General Hospital (LBJ), both located in Houston, Texas. Eligible patients were women aged 18 years and older who were able to speak and read English, who had a diagnosis of recurrent or primary high-grade invasive epithelial ovarian cancer, peritoneal cancer, or fallopian tube cancer confirmed by pathological analysis, and who provided written informed consent to participate. Patients with impaired performance status or a medical condition that precluded participation in the study, as judged by the physician, were excluded. The study was approved by the Institutional Review Boards of the participating institutions.

Two patient cohorts were consecutively recruited from 2010 to 2012. The first cohort, recruited only at MD Anderson, participated in the initial item-development stage of the MDASI-OC [18]; the second cohort, recruited at both MD Anderson and LBJ, participated in the judgment-quantification stage. Recruiting patients from LBJ allowed for inclusion of a more diverse population, as LBJ is a public hospital in the Harris Health System that primarily draws patients from low socioeconomic-status communities.

Demographic and clinical variable data collection

After informed consent was obtained, patients in both cohorts answered several questionnaires. A Measure of Global Quality of Life questionnaire was used to determine QOL. This single-item, self-reported questionnaire has been validated in numerous studies and is a simple, reliable method of measuring overall QOL [19–21]. The FACT-O also was completed by the patients in the second cohort. The FACT-O is a 38-item questionnaire used to evaluate the health-related QOL of patients with epithelial ovarian cancer. It has been demonstrated to provide reliable and valid QOL assessment of this patient population [7]. Patients in the first cohort completed an interview with six open-ended questions designed to elicit specific descriptions of the experience of having ovarian cancer. In the second cohort, patients completed the proposed MDASI-OC form. Additionally, the first 20 patients in the second cohort completed a cognitive debriefing questionnaire after completing the MDASI-OC.

Sociodemographic data (age, race, marital status, years of education, and employment status) were extracted from patient medical records. Trained clinical coordinators also recorded date of diagnosis, disease history, previous and current cancer treatments, current stage of disease, previous tumor response, comorbid conditions, current medications, Eastern Cooperative Oncology Group performance status (ECOG PS) rated at the time of questionnaire completion, and current laboratory values.

Symptom assessment

M. D. Anderson Symptom Inventory—The MDASI assesses the severity of 13 common (core) cancer-related symptoms: pain, fatigue (tiredness), nausea, disturbed sleep, being distressed, shortness of breath, difficulty remembering, lack of appetite, feeling drowsy, dry mouth, feeling sad, vomiting, and numbness or tingling. MDASI interference items assess how the symptoms interfere with six aspects of the patient's daily functioning: daily activity, mood, work, relations with others, walking, and enjoyment of life. MDASI modules contain the 13 core symptom items and six interference items of the MDASI, plus additional symptom items specific to a particular cancer type or treatment. The MDASI module for ovarian cancer was developed during this study.

The MDASI core and module symptom components ask the individual to rank symptom severity during the previous 24 hours on a scale of 0–10, with 0 being "not present" and 10 being "as bad as you can imagine." Interference is also assessed on a 0–10 scale, with 0 being "did not interfere" and 10 being "interfered completely." The core and interference items exhibited high levels of reliably (correlation coefficients between 0.82 and 0.91) in the original MDASI validation sample [10].

Development of the ovarian cancer module: The first patient cohort was used to establish the content domain for the MDASI-OC, described in depth elsewhere [18]. Briefly, individual qualitative interviews were conducted with 14 patients and lists of symptoms reported by patients in these interviews were reviewed by a panel of experts in gynecology and cancer. A final set of eight ovarian cancer-specific symptoms was added to the MDASI core symptom and interference items to create a provisional MDASI-OC for testing in the second cohort. Additional items included pain in the abdomen, feeling bloated, constipation, problem with paying attention (concentrating), urinary urgency, pain or burning with urination, back pain, and leg cramps or leg muscle pain.

Cognitive debriefing: The first 20 patients recruited in the second cohort participated in a structured cognitive debriefing interview after completing the provisional MDASI-OC. This interview assessed ease of completion, comprehensibility, acceptability, and redundancy of the MDASI-OC items. It also assessed whether any other important symptoms were excluded from the provisional module and how easy it was to recall symptoms experienced in the past 24 hours.

Statistical analysis

Descriptive statistics—Demographic and clinical characteristics are presented as means, standard deviations, and frequencies where appropriate. Prevalence of symptoms and ranked symptom severity were calculated for each MDASI core and module item.

Reliability of the MDASI-OC—Internal consistency reliability was assessed using Cronbach coefficient α. Time point 1 was the baseline observation and time point 2 was 3–8 days later.

Test-retest reliability was assessed via interclass correlations in a subset of 15 patients from the second cohort who had no current cancer treatment or prior chemotherapy within the last 30 days, in an effort to ensure limited interference from acute symptom changes due to treatment. Patients completed two MDASI-OC questionnaires within 24 hours, with the second assessment occurring at least four hours after the baseline assessment.

Validity of the MDASI-OC—Exploratory factor analysis was conducted to test for construct validity. Model fit was evaluated by examining the residuals using Bartlett's test of sphericity [22], the Kaiser-Meyer-Olkin measure of sampling adequacy [23], and Harman's criteria [24]. This analysis identified underlying constructs of symptoms in patients with ovarian cancer. The factor analysis was based upon principal axis factoring with direct oblimin rotation and a minimum eigenvalue of 1.

Known-group validity was used to determine whether the MDASI-OC is sensitive enough to differentiate between patients with good or poor ECOG PS. Student's t-test was used to assess the difference in mean symptom scores between patients with good performance status (ECOG PS = 0) and patients with poor performance status (EGOC PS ≥1).

Criterion (concurrent) validity was tested by correlating symptom severity and interference scores with the QOL and FACT-O subscales.

Results

Participant characteristics

Fourteen women were recruited for the first cohort; results from the MDASI-OC item-development phase are reported elsewhere [18]. Table 1 summarizes the demographic and clinical characteristics of the second cohort (n = 128) used for the psychometric validation of the MDASI-OC. Compared with LBJ patients, MD Anderson patients were less likely to belong to a minority race group and more likely to be married, to have a higher level of education, to be employed, to have better performance status, and to have received previous chemotherapy treatment. LBJ patients were more likely than MD Anderson patients to be treatment naïve.

MDASI core, ovarian module, and interference items

Results of the qualitative interviews and expert panel review suggested the addition of eight additional ovarian cancer-specific items (pain in the abdomen, feeling bloated, constipation, problem with paying attention, urinary urgency, pain or burning with urination, and leg cramps or leg muscle pains) [18]. Table 2 presents the severity and prevalence of the symptom (13 core and eight module) and interference items at baseline in the second patient cohort, in rank order from highest to lowest severity. Also shown are the frequencies of patients reporting no, mild, moderate, or severe symptoms. The top five symptoms reported by this population were fatigue, disturbed sleep, difficulty remembering things, numbness/tingling, and feeling distressed. Whereas fatigue was the most severe symptom report, a substantial portion of individuals reported moderate or severe levels of sleep disturbance.

Reliability

Results of the internal consistency reliability and test-retest reliability are shown in Tables 3. The MDASI-OC showed good internal consistency reliability, with Cronbach coefficient α values of 0.90 and 0.87 (time point 1 and time point 2, respectively) for the core + module components. Test-retest reliability was also excellent, with intra-class correlation values ranging from 0.88 to 0.96.

Validity

Bartlett's test of sphericity ($X^2 = 8676.7$; $p<0.001$) and the Kaiser-Meyer- Olkin measure of sampling adequacy (KMO = 0.93) indicated that factor analysis was appropriate in this sample. The pattern of factor loading from the factor analysis is shown in Table 4. The MDASI-OC has six underlying constructs: pain-related symptoms (back pain, pain in the abdomen, overall pain, disturbed sleep); cognitive problems (problem with paying attention/concentrating; difficulty remembering things, feeling drowsy); disease-related symptoms and numbness (numbness/tingling, shortness of breath, leg cramps or leg muscle pain, urinary urgency); treatment-related symptoms (vomiting, nausea, pain or burning with urination, dry mouth); affective issues (distress, feeling sad, fatigue); and gastrointestinal symptoms (constipation, lack of appetite, feeling bloated). Although these symptoms may not align nicely within well-defined constructs, the factor analysis presents suggestive evidence on how symptoms are reported by patients with ovarian cancer. These results demonstrate the instrument's ability to adequately assess symptoms commonly exhibited by women with ovarian cancer.

Known-group validity was demonstrated with ECOG PS ratings from 127 individuals (Table 5). The MDASI-OC was able to discriminate between patients with good (ECOG PS = 0) and poor (ECOG PS ≥1) performance status. Those with poor ECOG PS were significantly more symptomatic on the MDASI core, ovarian module, interference, and core + ovarian module subscales than were patients with good ECOG PS ($p<0.05$).

Comparisons to QOL and the FACT-O were made for 128 individuals (Table 5). Criterion validity results indicate the MDASI-OC correlated significantly with QOL and FACT-O scores ($p<0.001$). We also investigated the relationship between similar FACT-O and MDASI-OC items. Table 6 indicates a highly significant correlation ($p<0.0001$) between fatigue, nausea, pain, feeling sad, feeling nervous/distressed, swelling/feeling bloated, vomiting, and appetite items on the FACT-O and MDASI-OC.

Discussion

For the evaluation and development of new therapies or the comparison of existing therapies, there is a need for scales that focus on both cancer-related and treatment-related symptoms [25]. Symptom-specific scales like the MDASI and its modules may be more sensitive to clinical changes in cancer patients than are measures that sample the more-extensive domains of QOL [26]. MDASI modules offer several advantages over disease-specific symptom questionnaires. First, because all modules include the core MDASI symptom and interference items, data collected with modules can be used to compare symptom prevalence and severity across cancer types—a necessity for epidemiological studies and clinical trials that include patients with various cancer types. Researchers can easily identify the most consistently burdensome symptoms reported by patients by simply rank-ordering the severity of core symptom items from one type of cancer to another, thus providing an index of symptoms across cancers types. For example, the five most severe symptoms reported by our participants were fatigue, disturbed sleep, difficulty remembering things, numbness/tingling, and being distressed. All of these are core MDASI items that appear in modules for other cancer types [12–17]. This adaptability would not be possible for an instrument designed exclusively for patients with ovarian cancer. The MDASI was designed to assess symptoms common to cancer and its treatment; therefore, it is not surprising that many of the top symptoms will come from the MDASI core items.

Second, each MDASI module validation provides incremental evidence for the reliability, validity, and sensitivity of the core MDASI symptom and interference items. This is important because the development of new patient-reported outcome measures that will meet regulatory requirements is costly in time, effort, and expense. The repeated validation of these core items with each new module provides increasing evidence of the original MDASI in various cancer populations.

Third, the MDASI is available in several psychometrically and linguistically validated language versions [27–33]. Because each MDASI contains the core symptom and interference items, new modules require translation of only the module-specific questions. Further proof of the validity of the MDASI core items are the similar results in symptom ratings by cancer type made by patients responding to four different translations of the MDASI [34].

The FACT-O is a widely used, well-accepted questionnaire for determining QOL in patients with ovarian cancer [7]. However, the questionnaire is lengthy and could be burdensome to some patients. Additionally, variation in response direction can be confusing (lower scores may indicate a positive impact on QOL for some questions but a negative impact for others). MDASI scores are easily interpretable: a higher score always indicates an increase in severity, providing physicians and researchers an easy index to rate symptom burden. We demonstrated that the responses on the MDASI-OC are moderately to highly correlated to responses on the FACT-O, further demonstrating the MDASI-OC's validity.

The one limitation of this study is not addressing the MDASI-OC's ability to detect change, such as changes in symptoms when disease progresses or when treatment produces a

positive response. We do show that MDASI-OC responses are related to ECOG PS, which may indicate the MDASI-OC's ability to detect change. Additionally, it may be important to address whether changes in MDASI scores are reflective of disease progression or the side effects of treatment, something that may even be difficult for the patient to differentiate. The fact that we did not assess change over time affected our ability to assess whether that symptoms were attributable to the disease or treatment [25]. Therefore, our assertion that symptoms exhibited by those with ovarian cancer are due to treatment is only suggestive. Future studies with the MDASI-OC will address its ability to adequately measure these changes and will begin elucidating the causes of change.

Despite this one limitation, our study has many strengths in demonstrating the validity and reliably of the MDASI-OC. We used two distinct cohorts of patients with varying stages of ovarian cancer and previous-treatment statuses, thus expanding the generalizability of the psychometric properties of the MDASI-OC. Additionally, unlike other ovarian cancer assessment tools such as the FACT-O and the EORTC QLQ-OV28, the MDASI-OC is based on the concept of symptom burden rather than health-related QOL. Symptom-burden measures such as the MDASI-OC may be sufficient for patients, clinicians, and regulators to evaluate the symptomatic toxicities or benefits of new cancer therapies [35]. Finally, the MDASI-OC validation was conducted in accordance with FDA guidelines on instrument development. The authors are seeking FDA approval for regulatory use of the MDASI-OC [9].

Conclusion

The MDASI-OC module is a reliable, valid, sensitive instrument for assessing the severity of symptoms of ovarian cancer and the degree to which these symptoms interfere with patient functioning.

Acknowledgments

The authors acknowledge the editorial assistance of Jeanie F. Woodruff, BS, ELS, a scientific editor employed by the Department of Symptom Research at MD Anderson; Ms. Woodruff is supported with departmental funding.

This study was supported by Genentech and in part by the MD Anderson Cancer Center Support Grant from the National Cancer Institute of the National Institutes of Health (NIH/NCI P30 CA016672, PI: Ronald A. DePinho). Genentech provided support for the collection of data and analysis for the validation of the MDASI-OC. Partial salary support for Sonika Agarwal was provided by grant funding from the Hawn Foundation, Dallas, Texas. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Cancer Institute, the National Institutes of Health, or the Hawn Foundation.

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Research Highlights

- The M. D. Anderson Symptom Inventory (MDASI) assesses patient-reported symptoms.
- We validated a MDASI module for use in patients with ovarian cancer (MDASI-OC).
- The MDASI-OC is psychometrically valid, reliable, and sensitive to symptom change.

Table 1

Descriptive and clinical characteristics

	MD Anderson (*n* = 113)	LBJ Hospital (*n* = 15)	
	Mean (SD)	**Mean (SD)**	***p***
Age (years)	57.4 (13.2)	57.6 (8.8)	0.9652
Time since diagnosis (months)	43.2 (51.2)	21.3 (7.9)	0.1088
	n (%)	**n (%)**	***p***
Ethnicity			
Hispanic/Latino	18 (16%)	4 (27%)	0.300
Non-Hispanic/non-Latino	95 (84%)	11 (73%)	
Race			0.018
Asian	0 (0%)	0 (0%)	
Black	10 (9%)	5 (33%)	
Native American/Alaskan Native	0 (0%)	0 (0%)	
White	99 (88%)	10 (67%)	
Other	4 (3%)	0 (0%)	
Marital status			0.013
Married	75 (34%)	5 (67%)	
Not married	38 (66%)	10 (10%)	
Education			0.037
Less than high school	6 (5%)	1 (7%)	
High school graduate	30 (26%)	9 (60%)	
Some college	37 (33%)	5 (33%)	
College graduate	20 (18%)	0 (0%)	
Postgraduate	20 (18%)	0 (0%)	
Job status			<0.001
Employed full-time	34 (30%)	0 (0%)	
Employed part-time	7 (6%)	2 (13%)	
Homemaker	18 (16%)	2 (13%)	
Retired	33 (30%)	2 (13%)	
Medical leave of absence	3 (3%)	4 (27%)	
Disabled due to illness	11 (10%)	0 (0%)	
Unemployed	6 (5%)	5 (34%)	
ECOG PS			<0.001
0	74 (53%)	3 (16%)	
1	41 (29%)	5 (26%)	
2	14 (10%)	11 (58%)	
3	11 (8%)	0 (0%)	
Stage at diagnosis			0.459
I	10 (13%)	1 (8%)	

	MD Anderson (*n* = 113)	**LBJ Hospital (*n* = 15)**	
	Mean (SD)	**Mean (SD)**	***p***
II	11 (14%)	0 (0%)	
III	42 (53%)	9 (69%)	
IV	17 (21%)	3 (23%)	
Current treatment			0.717
Chemotherapy	59 (52%)	10 (67%)	
Radiation	2 (2%)	0 (0%)	
Surgery	2 (2%)	0 (0%)	
No treatment	49 (44%)	5 (33%)	
Previous chemotherapy	88 (78%)	8 (53%)	0.039
Previous radiation	8 (7%)	1 (7%)	0.953
Previous surgery	107 (95%)	13 (87%)	0.228
Treatment-naïve	2 (2%)	2 (13%)	0.016

Abbreviations: SD, standard deviation; ECOG PS, Eastern Cooperative Oncology Group performance status.

Table 2

Baseline symptom and interference items

Symptom	MDASI-OC section	Mean	SD	% None (0)[a]	% Mild (1–4)[a]	% Moderate (5–6)[a]	% Severe (7–10)[a]	Rank
Fatigue	Core	3.22	2.89	20	51	9	20	1
Disturbed sleep	Core	3.01	3.05	31	37	15	17	2
Difficulty remembering	Core	2.65	2.67	29	46	13	12	3
Numbness/tingling	Core	2.52	2.96	38	35	16	12	4
Being distressed	Core	2.34	2.74	41	38	9	11	5
Back pain	Module	2.2	2.8	48	32	9	12	6
Feeling bloated	Module	2.09	2.89	49	31	6	14	7
Constipation	Module	2.08	2.87	48	33	6	13	8
Feeling drowsy	Core	1.98	2.49	41	42	8	9	9
Pain	Core	1.98	2.98	54	28	6	12	10
Feeling sad	Core	1.91	2.51	45	39	7	9	11
Problem with paying attention	Module	1.9	2.48	43	41	9	7	12
Leg cramps or leg muscle pain	Module	1.89	2.59	47	38	6	9	13
Pain in the abdomen	Module	1.81	2.73	53	34	3	9	14
Urinary urgency	Module	1.8	2.88	55	28	4	13	15
Dry mouth	Core	1.74	2.67	59	23	8	10	16
Shortness of breath	Core	1.48	2.4	59	30	4	7	17
Lack of appetite	Core	1.27	2.25	65	23	5	6	18
Nausea	Core	0.93	2.15	75	16	4	6	19
Pain or burning with urination	Module	0.43	1.47	84	14	0	2	20
Vomiting	Core	0.41	1.67	93	2	2	3	21
Interference	**MDASI-OC section**	**Mean**	**SD**	**% None (0)[a]**	**% Mild (1–4)[a]**	**% Moderate (5–6)[a]**	**% Severe (7–10)[a]**	**Rank**
Work	Interference	2.24	2.93	45	34	9	12	1
Activity	Interference	2.02	2.81	51	31	6	12	2
Walking	Interference	1.78	2.63	52	33	6	9	3
Enjoyment of life	Interference	1.70	2.40	52	32	9	7	4

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Symptom	MDASI-OC section	Mean	SD	% None (0)[a]	% Mild (1–4)[a]	% Moderate (5–6)[a]	% Severe (7–10)[a]	Rank
Mood	Interference	1.68	2.33	49	37	9	5	5
Relations with others	Interference	0.96	1.74	65	27	5	2	6

Abbreviations: MDASI-OC, ovarian cancer module of the M. D. Anderson Symptom Inventory; SD, standard deviation.

[a]Rating on the MDASI-OC's 0–10 scale.

Table 3

Internal consistency reliability and test-retest reliability of the MDASI-OC at two timepoints

		Cronbach coefficient α		
Subscale	**Number of items**	**Time point 1 (*n* = 128)**	**Time point 2 (*n* = 98)**	**Intraclass correlation[a]**
Core	13	0.85	0.82	0.96
Ovarian module	8	0.80	0.77	0.88
Interference	6	0.89	0.90	0.98
Core + ovarian module	21	0.90	0.87	0.94

Abbreviation: MDASI-OC, ovarian cancer module of the M. D. Anderson Symptom Inventory.

[a] Administered within 24 hours in a subset of patients (*n* = 15)

Table 4

Construct validity of the MDASI-OC: factor analysis and underlying constructs

	Factors					
	1	**2**	**3**	**4**	**5**	**6**
Pain						
Back pain	**0.697**	−0.003	0.052	−0.115	0.062	0.039
Pain in the abdomen	**0.528**	0.066	−0.186	0.388	0.129	0.363
Pain	**0.470**	0.183	−0.035	0.297	0.192	0.156
Disturbed sleep	**0.349**	−0.027	0.037	0.166	0.137	0.045
Cognitive						
Problem with paying attention	0.018	**−0.736**	−0.001	0.050	0.214	0.134
Difficulty remembering	−0.115	**−0.617**	0.241	0.027	0.196	0.021
Feeling drowsy	0.355	**−0.447**	0.129	0.135	0.068	−0.051
Disease-related and numbness						
Numbness/tingling	−0.022	−0.057	**0.621**	−0.067	−0.019	−0.015
Shortness of breath	0.063	0.015	**0.515**	0.136	0.106	0.050
Leg cramps or leg muscle pain	0.114	−0.099	**0.433**	0.131	0.052	−0.001
Urinary urgency	0.331	−0.145	**0.338**	−0.009	−0.095	−0.001
Treatment-related						
Vomiting	0.021	−0.058	−0.034	**0.872**	−0.067	−0.171
Nausea	−0.017	0.191	0.192	**0.677**	0.061	0.120
Pain or burning with urination	−0.054	−0.086	−0.018	**0.443**	0.037	0.118
Dry mouth	0.154	−0.231	0.138	**0.278**	−0.175	0.153
Affective						
Being distressed	0.080	−0.046	0.122	−0.056	**0.888**	−0.039
Feeling sad	0.003	−0.310	−0.210	−0.003	**0.621**	0.177
Fatigue	0.277	−0.169	0.243	0.074	**0.398**	−0.140
Gastrointestinal						
Constipation	0.102	−0.166	−0.098	−0.032	0.017	**0.712**
Lack of appetite	−0.083	0.223	0.360	0.169	0.120	**0.483**

	Factors					
	1	**2**	**3**	**4**	**5**	**6**
Feeling bloated	0.423	−0.061	0.208	−0.048	−0.032	**0.441**

Abbreviation: MDASI-OC, ovarian cancer module of the M. D. Anderson Symptom Inventory.

Table 5

Known-group validity with MDASI-OC subscales and ECOG PS ratings and criterion (concurrent) validity with QOL and FACT-O

	ECOG PS						QOL		FACT-O	
	Good[a]		Poor[a]							
Subscale	**Mean**	**SD**	**Mean**	**SD**	**Diff**	***p***	**Pearson correlation**	***p***	**Pearson correlation**	***p***
Core	1.67	1.48	2.31	1.61	0.64	0.022	−0.268	0.002	−0.541	<0.001
Ovarian module	1.38	1.27	2.30	2.13	0.92	0.005	−0.230	0.009	−0.483	<0.001
Interference	1.19	1.43	2.41	2.42	1.22	0.001	−0.399	<0.001	−0.643	<0.001
Core + module	1.56	1.33	2.31	1.74	0.74	0.009	−0.265	0.002	−0.542	<0.001

Abbreviations: MDASI-OC, ovarian cancer module of the M. D. Anderson Symptom Inventory; ECOG PS, Eastern Cooperative Oncology Group performance status; QOL, Measure of Global Quality of Life questionnaire; FACT-O, Functional Assessment of Cancer Therapy-Ovary; SD, standard deviation.

[a]Good ECOG PS is defined as 0 and poor ECOG PS is defined as 1 or greater.

Table 6

Spearman correlations between FACT-O items and MDASI-OC items

FACT-O Item[a]	MDASI-OC Item[b]	Spearman's Rho	*p*
I have a lack of energy.	Your fatigue (tiredness) at its worst?	0.5483	<0.0001
I have nausea.	Your nausea at its worst?	0.6031	<0.0001
I have pain.	Your pain at its worst?	0.7551	<0.0001
I feel sad.	Your feeling sad at its worst?	0.6195	<0.0001
I feel nervous.	Your feelings of distressed (upset) at its worst?	0.4938	<0.0001
I am sleeping well.	Your disturbed sleep at its worst?	−0.6719	<0.0001
I have swelling in my stomach area.	Your feeling bloated at its worst?	0.7097	<0.0001
I have been vomiting.	Your vomiting at its worst?	0.4823	<0.0001
I have a good appetite.	Your lack of appetite at its worst?	−0.4907	<0.0001

Abbreviations: FACT-O, Functional Assessment of Cancer Therapy-Ovary; MDASI-OC, ovarian cancer module of the M. D. Anderson Symptom Inventory.

[a] FACT-O scoring from 0 (not at all) to 4 (very much).

[b] MDASI-OC scoring from 0 (not present) to 10 (as bad as you can imagine).