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

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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.

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ABSTRACT

Objective. The M. D. Anderson Symptom Inventory (MDASI) captures the severity of common cancer symptoms from the patient's 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 The University of Texas 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 a 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 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.

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Introduction

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

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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 the 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 (MDASI "modules"). MDASI modules have been developed for 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 the 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 h 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 reliability (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 h.

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