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Patient reported outcomes in evaluation of chemotherapy toxicity in women with gynecologic malignancies: A pilot study

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HIGHLIGHTS

- Using patient reported outcomes (PRO) may help providers identify symptoms in patients undergoing chemotherapy.
- Incorporating PRO into a gynecologic oncology clinic is feasible.
- Patients and providers have a high degree of satisfaction using PRO.
- Many patients and providers feel that using PRO improves clinical care.
- A 24-symptom questionnaire appropriately addresses important symptoms.

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ABSTRACT

Objective. Patient reported outcomes (PRO) relating to treatment toxicities have been demonstrated to reliably evaluate adverse events in clinical trials. We assessed the user satisfaction of implementing a focused PRO questionnaire for patients with gynecologic cancers undergoing chemotherapy.

Methods. Patients with gynecologic cancers undergoing chemotherapy were prospectively identified after IRB approval from April 2017 to August 2017. We administered a 24-symptom questionnaire, adapted from the validated PRO version of the Common Terminology Criteria for Adverse Event, to enrolled participants at the beginning of two outpatient visits. Patient and provider satisfaction with use of PRO was assessed afterwards. Descriptive statistics were performed.

Results. A total of 44 patients were enrolled. Patients were racially diverse: 52% Caucasian, 18% African-American, 9% Asian, and 20% other; 27% were of Hispanic origin. The majority of patients had ovarian cancer (54%), followed by uterine (29%) and cervical cancer (15%). Ninety-five percent of patient and 97% of provider satisfaction survey responses indicated the PRO questionnaire addressed important symptoms. Nearly all patient and provider responses indicated the PRO questionnaire was easy to use. Sixty-nine percent of patient and 97% of provider responses indicated the questionnaire positively impacted clinical care; 85% of patients wished to use a similar questionnaire throughout treatment.

Conclusions. We have shown that incorporating a focused patient-reported symptom questionnaire into routine outpatient care of gynecological oncology patients undergoing chemotherapy was met with a high degree of patient and provider satisfaction regarding questionnaire content, feasibility, and perception of care improvement.

1. Introduction

Assessing treatment-related toxicities among patients receiving chemotherapy is a routine aspect of any medical oncology practice. The traditional model of symptom monitoring requires providers to elicit and

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grade symptoms at each office visit. Paradigm shifts have led to the development of patient reported outcome (PRO) measures, allowing patients to use body system-based questionnaires to grade the severity of their symptoms on a subjective sliding scale. Clinical trials investigating therapy for malignancies now routinely incorporate PRO [1]. While instruments for assessing symptoms have been well integrated into clinical trial design, incorporation of standardized assessment of symptoms into routine clinical practice is less commonly performed [2].

Patients undergoing chemotherapy for gynecologic malignancies have frequent encounters with the healthcare system, presenting multiple opportunities to assess PRO. Evidence from non-cancer and solid tumor populations suggests that providers may miss symptoms or underestimate the severity of symptoms when relying on traditional provider-elicited models of assessing symptoms under a review of systems structure [3–8]. Utilization of a standardized patient-reported assessment of symptoms at the point of care may allow patients and providers to address issues important to patients that otherwise may not be prioritized [9]. Additionally, there can be patient discomfort with raising certain topics directly with their provider, which may be lessened through use of PRO [1].

Use of PRO in general practice has been studied in several non-gynecologic cancer populations. The benefits of assessing PRO in the outpatient setting include improving patient-provider communication, increasing physician awareness of symptoms, and facilitating improved symptom management [10, 11]. Mitigation of chemotherapy-related symptoms may also allow for longer treatment duration, as well as decreased emergency room visits and hospitalizations [12]. Additionally, PRO may inform patient-provider decision-making based on individual symptomatology and priorities, as well as aid in prognostication [1, 13–15].

Studies evaluating the feasibility of incorporating a PRO instrument into outpatient oncology settings have utilized various means of assessment including the Patient Reported Outcomes version of Common Terminology Criteria for Adverse Events (PRO-CTCAE) [8, 16, 17], Patient-Reported Outcomes Measurement Information System (PROMIS) [5, 18, 19], and Functional Assessment of Cancer Therapy (FACT) modules [20]. These feasibility studies have demonstrated that use of PRO is a non-burdensome method of assessing symptoms. Various modes of PRO delivery through paper, electronics, or telephone with administration at clinic or at home have also been explored [5, 8, 12, 16, 20, 21, 22], with research suggesting PRO measurement is equivalent across such modes of distribution [21]. Additional research by Basch, Deal [12, 23] has demonstrated that utilization of PRO improves health-related quality of life (QOL) and clinical outcomes, including a possible increase in overall survival for patients undergoing chemotherapy. This research was conducted in a solid tumor population and was not specific to a gynecologic oncology population undergoing chemotherapy.

To our knowledge, limited research has specifically focused on the utilization of a standardized PRO tool to assess chemotherapy toxicity in women with gynecologic malignancies. Enhanced knowledge of chemotherapy side effects may aid physician decision-making and allow providers to react more swiftly to developing issues than the traditional clinician-elicited model [11]. This study assesses the user satisfaction of implementing a focused PRO questionnaire for patients with gynecologic malignancies undergoing chemotherapy in a culturally diverse outpatient setting.

2. Methods

2.1. Enrollment

We performed a prospective single-arm pilot study to evaluate the use of a focused PRO questionnaire for patients with gynecologic cancers undergoing chemotherapy. Patients were eligible if they were at least 18 years old, undergoing outpatient chemotherapy for a gynecologic cancer, and able to read and understand English or Spanish. Eligible patients were identified through chart review of scheduled gynecologic oncology clinic patients. All participants provided informed consent in either English or Spanish prior to participation in the study. The gynecologic oncology providers caring for participating patients were consented as well. This study was approved by the Columbia University Institutional Review Board.

2.2. Study intervention

After providing consent, participants were asked to complete a demographics survey and a brief baseline survey that assessed opinions towards provider communication and care (Fig. 1). Additional demographic and clinical information were extracted retrospectively from medical records. Participants then completed a PRO symptom questionnaire prior to seeing their provider at two clinic visits. The questionnaire was administered on paper, electronically, or via telephone, depending on patient preference. A paper summary of symptom questionnaire responses was given to each clinic provider prior to seeing the patient. Following the second clinic visit, patient satisfaction and provider satisfaction were assessed with respective surveys.

2.3. Symptom questionnaire

The symptom questionnaire used to collect PRO in this study was derived from the PRO-CTCAE item library (Fig. 2). The PRO-CTCAE item library addresses 78 symptoms and was developed to measure patient-reported cancer treatment toxicity in adults undergoing outpatient chemotherapy or radiation [17]. We chose to use a questionnaire derived from the PRO-CTCAE item library given the results of the Basch, Deal [12] study, which also used a PRO-CTCAE-derived questionnaire. Consideration was given to use of existing gynecologic-specific questionnaires, such as FACT modules [24, 25], European Organization for Research and Treatment of Cancer (EORTC) [26–28], and M.D. Anderson Symptom Inventory (MDASI) [29] modules. Ultimately, such gynecologic-specific questionnaires were not used due to their lack of focus on chemotherapy toxicity or their lack of generalizability to all gynecologic cancer types.

A total of 24 symptoms were selected from the PRO-CTCAE item library to be included in the questionnaire. These 24 symptoms included the National Cancer Institute's designated 12 core symptoms [30], as well as 12 additional items chosen by a team of providers to reflect important treatment-related toxicities, and physical and neuropsychological symptoms that have been associated with lower QOL [30–33]. The option to report additional symptoms was also available.

The questionnaires were available in English or Spanish. For all but one question, responses were graded on a 5-point Likert scale addressing frequency, severity, or interference with daily activities. Questionnaires administered via paper contained fifty questions (Supplemental Fig. 1). Questionnaires administered via email and telephone used branching technology to allow for as few as 25 questions.

2.4. Outcomes

Our primary objective was to characterize patient and provider satisfaction with the symptom questionnaire. Surveys evaluating patient and provider satisfaction were administered at the conclusion of the study. These surveys were designed to gauge satisfaction with use of the symptom questionnaire across three domains: *content of questionnaire, feasibility of using the questionnaire in an outpatient setting, and perceived impact of the questionnaire on clinical care.* Each satisfaction survey item was evaluated on a 4-point Likert scale (strongly agree/agree/disagree/strongly disagree), with an additional "Not Applicable" option.

Within the satisfaction survey, content of the questionnaire was assessed for appropriateness and comprehensiveness. Three items were used in the patient satisfaction survey and two items were used

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