Gynecologic Oncology xxx (2018) xxx–xxx

Contents lists available at ScienceDirect

Gynecologic Oncology

journal homepage: www.elsevier.com/locate/ygyno

Validation of PROMIS emotional distress short form scales for cervical cancer

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HIGHLIGHTS

- PROMIS depression and anxiety short forms reliably and validly assess cervical cancer-specific emotional distress.
- PROMIS depression and anxiety short forms perform as well or better than legacy measures among cervical cancer survivors.
- The depression short form demonstrated sensitivity to change over time.

ARTICLE INFO

Article history:
Received 15 May 2018
Received in revised form 21 July 2018
Accepted 29 July 2018
Available online xxxx

Keywords:
Patient-reported outcomes
Cervical cancer
Depression
Anxiety

ABSTRACT

Objectives. Cervical cancer patients are at high risk for emotional distress. In this study we evaluate the PROMIS emotional distress-Depression and -Anxiety Short Forms for assessing depression and anxiety in a cervical cancer population.

Methods. A 15-item questionnaire was used in a cervical cancer biobehavioral randomized clinical trial, testing psychosocial telephone counseling (PTC) against usual care (UC). It was administered to 204 patients prior to randomization, four months post-enrollment, and nine months post-enrollment, together with legacy measures of depression. The short forms were evaluated in patients participating in this study over three time points for internal consistency, convergent validity, and responsiveness to change over time.

Results. Overall, 45% and 47% of patients scored in the moderate to severe range for anxiety and depression, respectively. Internal consistency coefficients were ≥ 0.95 at baseline, 4 months, and 9 months for depression and anxiety. The average inter-item correlation was 0.65 and 0.73 at baseline assessment for depression and anxiety, respectively. The depression short form T-score was correlated with legacy distress scales ranging from 0.44–0.76, and the anxiety short form ranging from 0.45–0.78. The depression short form demonstrated sensitivity to change as patients randomized to the counseling intervention reported greater improvement over time in depression ($p = 0.014$), and a nonsignificant improvement in anxiety, compared to the patients receiving usual care.

Conclusions. The PROMIS depression and anxiety short forms reliably and validly assess cervical cancer-specific emotional distress, capture salient features of distress in this population, and perform as well or better than legacy measures.

1. Introduction

Cervical cancer survivors experience quality of life (QOL) disruptions which are often severe and prolonged [1–3]. This disruption can include compromised emotional well-being [4–6]. The majority of clinical studies that assess QOL in cervical cancer patients generally report changes over time in physical, functional, or symptom-specific concerns [7–9], without specific reference to emotional well-being or distress. It is notable however, that in 2014 the American Society of Clinical Oncology (ASCO) issued guidelines reinforcing the need to care for psychological needs of cancer survivors, specifically recommending that all people who have been treated for cancer be evaluated for symptoms of depression and anxiety. This premise is contained in Quality Oncology Practice Initiative (QOPI) certification, which recognizes that a

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https://doi.org/10.1016/j.ygyno.2018.07.022
0090-8258/

patient's emotional well-being should be assessed and documented in the chart, thereby demonstrating commitment to delivering the highest quality of cancer care.

Emotional distress may well deserve even greater attention in the context of cervical cancer care and survivorship, since distress in this population is frequently associated with advanced disease, long-term treatment sequelae, and lower socioeconomic status [6,10,11], and is likely to be associated with poor treatment compliance [12,13]. PROMIS emotional distress short forms have previously been noted to reliably and validly assess depression and anxiety in several disease contexts [14–19]. Moreover, a cancer-specific PROMIS module has been created [20] which incorporates the emotional distress short forms and has shown to converge with expert clinical judgement [21], be appropriate in a variety of cancer settings [22] and several different modes of administration [23].

Results from a biobehavioral randomized trial demonstrated an improvement in emotional distress, as measured by PROMIS short forms of depression and anxiety, among cervical cancer patients randomized to a psychosocial telephone counseling (PTC) intervention, compared to those who received usual care [25]. The improvement was most evident between the baseline and four-month assessment interval, which coincided with 'active treatment.' These study results helped to reaffirm the importance of addressing emotional distress in the cervical cancer population; second, they indicated that emotional distress is amenable to change and improvement; and third, they demonstrated that use of a psychometrically sound measure of distress, appropriate to the sociodemographic and disease characteristics of this population, can provide a robust and significant contribution to study and treatment planning. The evaluation of psychometric properties and performance of the PROMIS emotional distress short forms administered in this randomized trial [25] is the subject of the current report, and adds to the body of literature noting the importance of emotional well-being measurement among cervical cancer patients.

2. Materials and methods

2.1. Study population

Our biobehavioral study sought to determine if the use of PTC could improve patient-reported outcomes, compared to usual care. Primary and secondary objectives, patient eligibility, recruitment and retention, and details of PTC administration and results were previously published [5,25]. Survivors of cervical cancer were identified from the California Cancer Registries (Orange, Los Angeles, Imperial, and San Diego Counties). Eligibility criteria were 1) stage 1 to IVA cervical cancer (locally advanced but without disseminated metastasis), 2) completion of definitive treatment at least 2 months earlier, and 3) ability to speak and read English or Spanish. Exclusion criteria were 1) treatment with biologic response modifiers or prior immunotherapy within 4 weeks of study enrollment, 2) treatment with investigational drugs within 30 days, 3) required corticosteroids, and 4) immunosuppression. After passive physician approval for contact, eligible survivors were contacted via mail and telephone. Participants were enrolled in the trial at ≥9 and <30 months from diagnosis. All patients provided informed consent consistent with all federal, state and local requirements prior to enrolling in the study.

Patients were stratified based on language preference (English or Spanish) and randomly allocated to PTC or usual care. The PTC counseling intervention was, in general, conducted weekly for five weeks with a one-month booster session. The short-term outcome was assessed four months after study enrollment. A longer-term outcome was assessed nine months after study enrollment.

2.2. Measures

2.2.1. PROMIS emotional distress short forms

The PROMIS emotional distress short forms (SF) consist of 15 items, 8 items on depression (Depression – Short Form 8a) and 7 items on anxiety (Anxiety – Short Form 7a). PROMIS measures were developed, beginning in 2004, out of a collaborative process funded by the National Institutes of Health (NIH) Roadmap for Medical Research Initiative [26]. Mental health (along with physical functioning, fatigue, pain, and social participation) was identified as a core patient-reported outcome early in the development process. Using expert review and quantitative analysis of existing data, the PROMIS steering committee identified emotional distress as a key domain of mental health, and defined its three subdomains as depression, anxiety, and anger. Depression was defined as "low levels of positive affect," anxiety as "autonomic arousal and experience of threat," and anger as "hostility," "cynicism," and "frustration" regarding "goal-directed behavior" [27].

Each item in the PROMIS emotional distress SF was scored from 1 to 5 points where 1 = never, 2 = rarely, 3 = sometimes, 4 = often, and 5 = always. Consistent with PROMIS scoring convention, the scale score was computed using proration when >50% of items were answered. A high score on these PROMIS short forms connotes more emotional distress (i.e., more depression or anxiety). With a standardized normative T-score of 50 and a standard deviation of 10, T-scores <55 would translate as normal; 55–60 as mild; 60–70 as moderate, and ≥70 as severe distress [28].

2.2.2. Legacy measures

PROMIS short form scales are substantially shorter, and thus may confer an advantage over many legacy measures. The following legacy measures were included in this study to demonstrate relationships between PROMIS depression and anxiety short-form scales and legacy measures which could be related to mood.

The Functional Assessment of Cancer Therapy-Cervical (FACT-Cx) is a multidimensional, combined generic and disease-specific QOL questionnaire for cervical cancer patients. The FACT-G (general) questionnaire (version 4) is a 27-item self-report measure developed specifically for cancer patients and designed for use in a variety of settings [29]. It consists of four subscales (physical well-being (PWB), social well-being (SWB), emotional well-being (EWB), functional well-being (FWB)) that can be analyzed separately or summed to produce a total QOL score. Eleven additional items represent cervical cancer-specific problems. The FACT Trial Outcome Index (FACT-TOI) is the sum of the FACT subdomains PWB, FWB and cancer-specific concerns. The Brief Symptom Inventory (BSI-18) [30] is a shortened version of the BSI, developed to assess psychological distress. Each item is rated on a 5-point Likert scale from 0 (not at all) to 4 (always). Patients are asked to respond to each item in terms of "how they have been feeling during the past 7 days." The BSI-18 includes subscales measuring depression, anxiety, and somatization, as well as an overall total score.

The Impact of Event Scale (IES) [31] is a 15-item Likert scale to measure distress related to cancer. The IES has two sub-scales: (a) intrusive thoughts and feelings, and (b) avoidance of thoughts and feelings related to the stressful situation. The 10-item Perceived Stress Scale (PSS) assesses perceptions of stress over the past month [32] [33]. Items reflect how frequently the patient experienced a specific feeling/state, and are rated on a 5-point Likert scale (0 = never to 4 = very often). The Medical Outcomes Survey Social Support (MOS-SS) questionnaire, a 19-item multidimensional, self-administered survey of social support was developed for the Medical Outcomes Survey for patients with chronic conditions [34]. Responses are ranked on a Likert scale from 1 (none of the time) to 5 (all of the time), and indicate how often respondents perceive the availability of a particular source of support.

Please cite this article as: J. Wilford, et al., Validation of PROMIS emotional distress short form scales for cervical cancer, Gynecol Oncol (2018), https://doi.org/10.1016/j.ygyno.2018.07.022