Original Article

Minimal Clinically Important Difference in the Physical, Emotional, and Total Symptom Distress Scores of the Edmonton Symptom Assessment System

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Abstract

Context. The Edmonton Symptom Assessment System (ESAS) is one of the most commonly used symptom batteries in clinical practice and research.

Objectives. We used the anchor-based approach to identify the minimal clinically important difference (MCID) for improvement and deterioration for ESAS physical, emotional, and total symptom distress scores.

Methods. In this multicenter prospective study, we asked patients with advanced cancer to complete their ESAS at the first clinic visit and at a second visit three weeks later. The anchor for MCID determination was Patient's Global Impression regarding their physical, emotional, and overall symptom burden ("better," "about the same," or "worse"). We identified the optimal sensitivity/specificity cutoffs for both improvement and deterioration for the three ESAS scores and also determined the within-patient changes.

Results. A total of 796 patients were enrolled from six centers. The ESAS scores had moderate responsiveness, with area under the receiver operating characteristic curve between 0.69 and 0.76. Using the sensitivity-specificity approach, the optimal cutoffs for ESAS physical, emotional, and total symptom distress scores were $\geq 3/60$, $\geq 2/20$, and $\geq 3/90$ for improvement, and $\leq -4/60$, $\leq -1/20$, and $\leq -4/90$ for deterioration, respectively. These cutoffs had moderate sensitivities (59%−68%) and specificities (62%−80%). The within-patient change approach revealed the MCID cutoffs for improvement/deterioration to be $3/-4.3$ for the physical score, $2.4/-1.8$ for the emotional score, and $5.7/-2.9$ for the total symptom distress score.

Conclusion. We identified the MCIDs for physical, emotional, and total symptom distress scores, which have implications for interpretation of symptom response in clinical trials. J Pain Symptom Manage 2016;51:262−269.

Key Words

Neoplasms, outcome measures, pain, sample size, sensitivity and specificity, symptom assessment

Introduction

Patients with advanced cancer develop a multitude of physical and emotional symptoms over the course of their illness.[1] Undetected and untreated symptoms could worsen over time, with a negative impact on patients' function and quality of life. Routine

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symptom assessment thus represents the key to effective symptom management.[2]

The Edmonton Symptom Assessment System (ESAS) is a validated 10-item symptom battery that assesses seven physical symptoms, two emotional symptoms, and overall well-being.[3] Since its first publication in 1989, it has been translated and used for symptom assessment in numerous countries worldwide. The ESAS is often used for symptom screening and longitudinal assessment in both clinical and research settings.[4–11]

One important question regarding the ESAS is how much of a change is clinically significant. We recently reported the minimal clinically important difference (MCID) for each ESAS symptom individually.[12] However, many clinical trials report combined ESAS scores (physical, emotional, and total) instead of individual symptoms. For example, two randomized controlled trials that compared early palliative care to routine oncologic care in a cluster-randomized control trial included the ESAS total symptom distress score as an outcome.[13,14] To date, the MCIDs for ESAS physical, emotional, and total scores have not been determined. A better understanding of the MCID of ESAS combined scores has important implications for evaluation of symptom response. In this multicenter prospective study, we determined the MCID for improvement and deterioration of ESAS physical, emotional, and total symptom distress scores using the anchor-based approach.

Methods

Participants

This is a secondary analysis of a prospective, multicenter, longitudinal observational study that examined the MCID for individual ESAS items. Here, we focus on the MCID for ESAS scores. We have described the study design and methods in detail previously.[12] Briefly, patients were eligible for this study if they had a diagnosis of advanced cancer, defined as locally advanced, recurrent, or metastatic disease; were aged 18 years or older; were seen at an outpatient clinic at one of the six participating centers and had a scheduled clinic visit 14–34 days after the first study visit; and did not have delirium (Memorial Delirium Assessment Scale of 13 or greater). The institutional review boards at all participating centers approved the study. All participants provided written informed consent. Study enrollment occurred between December 8, 2011 and April 30, 2014.

The participating centers were as follows: 1) M. D. Anderson Cancer Center, Houston, TX, USA; 2) King Hussein Cancer Center, Amman, Jordan; 3) Barretos Cancer Hospital, Barretos, Brazil; 4) Pontificia Universidad Catolica de Chile, Santigo, Chile; 5) Kangdong Sacred Heart Hospital, Seoul, Republic of Korea; and 6) Tata Memorial Center, Mumbai, India. As stated previously, all participants were enrolled at palliative care outpatient clinic consultation with the following exceptions: Korean patients were enrolled from oncology clinics; a small proportion of Brazilian patients were enrolled at an outpatient palliative care follow-up visit; and U.S. patients were consented during their first follow-up clinic visit because all assessments for the first study visit were routinely collected at consultation. These minor variations in inception cohort provided us with a more diverse patient population to determine MCID and increased its generalizability.

Data Collection

In addition to baseline demographics, we collected ESAS data during both the first and second clinic visits. ESAS is a validated symptom battery that assesses the average intensity of 10 symptoms (pain, fatigue, nausea, depression, anxiety, drowsiness, shortness of breath, appetite, feelings of well-being, and sleep) over the past 24 hours, each with an 11-point numerical rating scale that ranges from 0 (no symptom) to 10 (worst intensity).[3] It has been translated into the languages of respective countries by MAPI Research Trust (i.e., English, Arabic, Portuguese, Spanish, Korean, and Hindi) and validated both linguistically and psychometrically.[5,8,11,15,16]

In clinical trials that assess symptom burden using the ESAS, the symptom burden is often represented using the physical score, emotional score, and a total score.[17] The physical score ranges between 0 and 60, representing the sum of ESAS pain, fatigue, nausea, drowsiness, dyspnea, and loss of appetite. The emotional score consists of both anxiety and depression (total 0–20). The total symptom distress score represents the combination of physical and emotional scores as well as well-being (total 0–90). Higher scores indicate higher symptom burden.

The benchmark for whether patients considered their physical, emotional, and total symptom burden improved was based on the Patient's Global Impression Scale (PGI), which was collected at the second study visit. The PGI is a validated global rating of change scale used to evaluate patients' subjective response at the second visit.[18,19] Patients were asked three questions: "How is your physical symptom burden/emotional symptom burden/total symptom burden over the last 24 hours compared to your last visit?" Response choices were "better," "about the same" or "worse." If the patient responded with "better," they were then asked "How much better?" ("much better," "better," "a little better"). If the patient responded with "worse," they were then asked