Journal of Psychosomatic Research 75 (2013) 160–166

Contents lists available at ScienceDirect

Journal of Psychosomatic Research

Temporal trends in symptom experience predict the accuracy of recall PROs

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ARTICLE INFO

Article history:
Received 10 March 2013
Received in revised form 13 June 2013
Accepted 16 June 2013

Keywords:
Electronic diaries
Patient-reported outcomes
Recall bias
Temporal trends

ABSTRACT

Objective: Patient-reported outcome measures with reporting periods of a week or more are often used to evaluate the change of symptoms over time, but the accuracy of recall in the context of change is not well understood. This study examined whether temporal trends in symptoms that occur during the reporting period impact the accuracy of 7-day recall reports.
Methods: Women with premenstrual symptoms (n = 95) completed daily reports of anger, depression, fatigue, and pain intensity for 4 weeks, as well as 7-day recall reports at the end of each week. Latent class growth analysis was used to categorize recall periods based on the direction and rate of change in the daily reports. Agreement (level differences and correlations) between 7-day recall and aggregated daily scores was compared for recall periods with different temporal trends.
Results: Recall periods with positive, negative, and flat temporal trends were identified and they varied in accordance with weeks of the menstrual cycle. Replicating previous research, 7-day recall scores were consistently higher than aggregated daily scores, but this level difference was more pronounced for recall periods involving positive and negative trends compared with flat trends. Moreover, correlations between 7-day recall and aggregated daily scores were lower in the presence of positive and negative trends compared with flat trends. These findings were largely consistent for anger, depression, fatigue, and pain intensity.
Conclusion: Temporal trends in symptoms can influence the accuracy of recall reports and this should be considered in research designs involving change.

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Introduction

The ability of patient-reported outcomes (PROs) to accurately depict patients' experiences of health and wellbeing is of critical importance for quality of life research. One key issue for maximizing accuracy is the selection of appropriate recall periods for PRO measurement [1,2], that is, the period of time over which respondents are asked to recollect. The most commonly used instruments ask patients to summarize their experiences over many days, for example, the past 7 days. This is often deemed useful to capture a clinically relevant window of time with a single assessment [2,3]. However, evidence suggests that recall ratings are impacted by a number of contextual factors [4] and memory biases [5,6].

To what extent the length of recall impacts the accuracy of PROs has been examined in a number of studies, with mixed results. Some studies suggest that recall periods beyond one day show considerable distortions [1,7], yet others have found reasonably high correspondence between real-time or daily assessment and recall ratings of a week or more [8–11]. An important limitation of many prior studies is that they were conducted with samples whose symptoms were constant or in a "steady state", as opposed to symptoms that had systematic change (increases or decreases) over time. There has been a lingering concern that results from these studies may not adequately depict the accuracy of recall PROs where change is expected, for example, when PROs are used to evaluate health-related developmental processes or treatment effects in clinical trials [1,8].

There are several reasons to suspect that the accuracy of recall PROs may be affected by temporal trends of experiences during the recall period. Cognitive theory suggests that due to limitations of human memory, people often rely on mental shortcuts and provide ratings consistent with their global impression of the period as a whole. The rate at which experiences of health and quality of life improve or worsen over time is an important aspect of the overall "gestalt" of the recall period [12,13]. Behavioral decision-making research has demonstrated that people's satisfaction with hypothetical episodes is influenced by the extent to which an episode becomes more pleasant or unpleasant as it unfolds [14,15]. In addition, change is of fundamental importance to the

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http://dx.doi.org/10.1016/j.jpsychores.2013.06.006

sensitivity of perceptual systems; for example, when presented with a static visual image, visual perception fades quickly in the absence of change [16].

The goal of this study was to examine whether the accuracy of 7-day recall PROs is influenced by temporal trends of daily symptom experience during the recall period. The data are from a larger study comparing recall and daily PROs across several populations. The present study sample consists of women reporting premenstrual symptoms, for whom a monthly cyclical pattern of symptom change is expected [17,18]. Women provided daily assessments of anger, fatigue, depression, and pain intensity over the course of 4 weeks, and were administered 7-day recall assessments for each of these PRO domains at the end of each week. Recall periods were classified in accordance with the direction and rate of change of daily symptoms using latent class growth analysis and the accuracy of 7-day recall PROs was compared in groups defined by different temporal trends of daily symptoms.

In accordance with prior research, we expected that 7-day recall measures would generally yield higher symptom levels compared to the average of daily assessments [1,8,19]. The critical question was whether this effect would be accentuated or attenuated for different temporal trends. In addition, we examined whether the correspondence (i.e., correlation) between 7-day recall and aggregated daily assessments would be affected by temporal trends of daily experience [1].

Methods

Participants

One hundred women were recruited for this study. Eligibility criteria were age ≥21 years, availability to make daily ratings for 28 consecutive days, high-speed Internet access at home, English fluency, no visual impairment, no night shift job, no hysterectomy, regular monthly menses, not pregnant, and not currently using hormone replacement therapy or fertility drugs. In addition, women were required to report ≥2 physical premenstrual symptoms (abdominal bloating, weight gain from water retention, increase in appetite/food cravings, breast pain/tenderness, acne flare-ups, hot flashes, headache, dizziness, poor coordination, change in sex drive, constipation/diarrhea) and ≥1 emotional/behavioral symptom (irritability/angry outbursts, mood swings or depressed mood, poor impulse control, tension/anxiety, lethargy, insomnia, crying, social withdrawal, trouble concentrating or thinking clearly, thirst). The symptoms were required for the past 3 menstrual cycles; they had to occur during 5–7 days before menses and to fade by the end of menses [18].

Procedure

The study was approved by the Stony Brook University Institutional Review Board. Recruitment was conducted from Eastern and Central US time zones using an Internet panel of 1.7 million respondents who regularly participate in online surveys (www.surveyspot.com). Panelists pre-screened for premenstrual symptoms were invited to contact our office for eligibility screening. Participants provided electronic consent and were telephone-trained on how to complete the assessments on their home computers. Data were collected online using Assessment Center℠ (http://www.assessmentcenter.net/), a free research management tool. Participants were instructed to complete the daily ratings over 28 days between 6 PM and midnight. The 7-day recall measures were administered prior to the daily measures at the end of each week (days 7, 14, 21, and 28). The protocol started approximately two weeks before the women's estimated first day of her next menses to increase the likelihood of obtaining data for a full week before and after menses. Compliance was monitored daily and participants were contacted if they missed an assessment. Participants received up to $150 for study completion.

Measures

Anger, fatigue, and depression

Anger, fatigue, and depression were assessed with measures provided by the National Institutes of Health funded Patient-Reported Outcomes Measurement Information System (PROMIS) initiative [3,20,21]. PROMIS has developed item-banks (i.e., comprehensive sets of calibrated items) using a strategic item generation and selection methodology (including focus groups and cognitive interviews) and employed extensive psychometric testing using item response theory (IRT) [22,23]. PROMIS measures maintain high precision (reliability ≥ .95) over wide ranges of the PRO severity continuum [20,24]. PROMIS uses a 7-day recall period for the domains in this study (anger, fatigue, depression). The scores are normed on a T-score metric, which is scaled to have a mean of 50 and a standard deviation of 10 in the U.S. general population [3,25].

PROMIS affords measurement via Computerized Adaptive Testing (CAT) or by selecting any subset of items from the bank to create a static short-form [3]. In the present study, the 7-day recall PROMIS measures were administered via CAT, which adaptively tailors the selection of items to optimize measurement precision and stops when sufficient precision (standard error < 0.3, equaling reliability > .90) has been achieved (no less than 4 and no more than 12 items were administered for each domain) [24].

Daily versions of PROMIS measures were administered as static short-forms consisting of 8 (anger), 7 (fatigue), and 8 (depression) items. The reporting period of each PROMIS item was changed from "In the past 7 days…" to "In the last day…"; item content and response options were left unchanged. The items were taken from the PROMIS Version 1 short-forms [20,21], with the exception of two fatigue items with wordings not suitable for daily assessment (these items were substituted by other calibrated items from the fatigue bank [20]). The daily measures were scored with IRT using the national item parameters established for PROMIS (http://www.nihpromis.org). This placed the daily scores on the PROMIS T-score metric and thereby allowed for a direct comparison of daily and 7-day recall scores on the same metric [19].

Pain intensity

Pain intensity was measured on a standard 0–10 numeric rating scale (NRS; 0 = no pain, 10 = worst pain imaginable) using parallel versions for daily and 7-day recall assessments [26,27].

Days of menses

Days of menses were assessed with the daily question: "Did you have any menstrual bleeding today?" (Yes — No).

Analysis strategy

Data analysis proceeded in two consecutive steps. The purpose of step 1 was to classify the participants' 7-day recall periods based on the temporal trends underlying the daily scores. Latent class growth analysis (LCGA) was used for this purpose. The prevalence of the identified temporal trends across the weeks of the menstrual cycle was examined to validate the LCGA solution. In step 2, we analyzed whether agreement (level differences and correlations) between 7-day recall and aggregated daily scores differed across the types of temporal trends derived from the LCGA. It is noteworthy that the classification of temporal trends was entirely independent of the analyses in step 2.

Latent class growth analysis of daily scores

LCGA is similar to latent growth curve analysis in estimating change represented by latent intercept and slope coefficients. However, instead

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