The Effects of Granular Patient Reported Outcomes on Pain Intensity and Interference in Individuals with Chronic Low Back Pain

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INTRODUCTION: Chronic low back pain (cLBP) is a multifaceted condition that requires a patient-centered personalized care approach to drive treatment outcomes and reinforce positive behavioral change.[1] Patient-reported outcomes (PROs) are utilized to include the patient's perspective to drive treatment pathways and are essential to assess the impacts of cLBP.[1,2] While PROs are commonly used to evaluate cLBP, the consensus as to what measures best assess patient outcomes remains unknown.[1] Commonly used PRO measurements are the PEG-3 questionnaire for pain intensity and interference, and the painDETECT questionnaire for neuropathic pain components specifically in LBP.[3,4] Ecological Momentary Assessment (EMA) is a method of using PROs to evaluate pain experiences when patients are functioning within their natural environments.[5] The purpose of this study was to compare PRO responses collected through standard questionnaires and EMA from participants with cLBP to determine if higher levels of granularity in reported pain intensity and pain interference data visually correspond to participant-selected descriptors of pain.

METHODS: This IRB-approved study involved 12 adult participants with cLBP (Females: N=10, 39.4 ± 16.2 years; Males: N=2, 47.0 ± 21.0 years), defined as LBP >12 weeks and occurring over 50% of the time, were recruited and consented to a 7-day observational period. Participants completed the PEG-3 and painDETECT Pain Course Pattern (PCP) questionnaires before and after the 7-day period. During the observational period, participants used a smartphone app called "LB3P In-Home" to answer several EMA questions. The two questions used in this study were: "Rate your level of low back pain right now" (pain intensity), and "Rate how much your pain is interfering with what you are doing right now" (pain interference). EMA responses were collected during the morning, afternoon, and evening each day during the 7-day period. Both PEG-3 and EMA questions were scored on a 0 (no pain) – 10 (worst pain imaginable) scale. The painDETECT PCP section asked participants to select one of four visual graphs that best described their pain.

Two different types of analysis were completed. (Part 1) The average and standard deviation PEG-3 scores were compared against the 12 individualized cLBP EMA data points for both pain intensity and pain interference. The percentage of recorded EMA data points that were outside of the ± one standard deviation PEG-3 range was calculated. (Part 2) Individualized data from PEG-3 and EMA questionnaires were compiled in a graphical format separately for all participants and matched with corresponding painDETECT PCP descriptors over the 7-day period.

RESULTS: (Part 1) 56.10% of data points were not within ± one standard deviation of PEG intensity scores (Before Avg: 3.42, After Avg: 3.33, S.D.: 1.27) (Figure 1), and 46.43% of data points were not within ± one standard deviation of PEG interference scores (Before Avg: 2.92, After Avg: 2.75, S.D.: 2.52) (Figure 2). (Part 2) Of the 12 participant individualized graphs created to visually display PEG-3 and EMA data matched with the painDETECT PCP section, one example was selected and displayed (Figure 3). Of the PCP selection data, the results were: Persistent Pain with Slight Fluctuations (5 participants); Persistent Pain with Pain Attacks (1 participant); Pain Attacks without Pain Between them (1 participant); Pain Attacks with Pain Between them (2 participants); Persistent Pain with Pain Attack *transitioning to* Persistent Pain with Slight Fluctuations (2 participants); Pain Attacks without Pain Between them *transitioning to* Persistent Pain with Slight Fluctuations (1 participant).

DISCUSSION: This analysis suggests that EMA data provides a more descriptive representation of pain intensity and pain interference and visually correlates with painDETECT PCP descriptions. EMA can capture the fluctuations in pain intensity and pain interference experienced by individuals over a 7-day period, and a large percentage of pain intensity and pain interference data points are not likely captured through standard instruments such as PEG-3. Limitations to this study include a small sample size which limited the ability to carry out formal statistical comparisons. Future research will evaluate relationships between EMA data collected daily and other PRO's as well as what frequencies EMA should be collected. However, EMA data shows promise in measuring response to just-in-time adaptive interventions and delivering support during the moment and in the context that the person needs it most.[6]

CLINICAL SIGNIFICANCE: Using EMA to collect PROs may provide granular descriptions of pain in people with cLBP and may inform both applications of just-in-time adaptive interventions and tailored treatment pathways.

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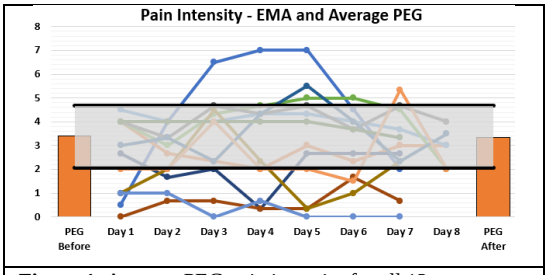

Figure 1. Average PEG pain intensity for all 12 participants and individualized EMA pain intensity scores. Shaded region represents data within ± one standard deviation of mean; 56.10% of the data is not in this range.

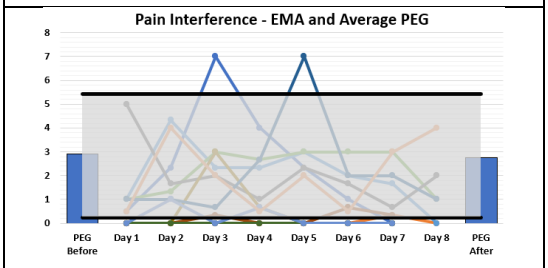

Figure 2. Average PEG pain interference for all 12 participants and individualized EMA pain interference scores. Shaded region represents data within ± one standard deviation of mean; 46.43% of the data is not in this range.

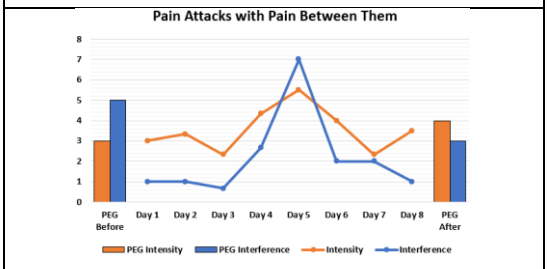

Figure 3. Graphical comparison of PEG-3 and EMA data for one participant in the "Pain Attacks with Pain Between Them" PCP category. Bars represent PEG-3. Lines represent EMA. Orange is pain intensity. Blue is pain interference.