Assessment of Longitudinal Clinical Outcome Measures for Chronic Low Back Pain over 12 Months

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INTRODUCTION

The National Institutes of Health Task Force on Research Standards for Chronic Low Back Pain (NIH RTF) identified low back pain intensity, back-related functioning, and quality of life as important clinical outcome domains.[1] The RTF recommended that research be conducted on the performance of corresponding measures in these domains, including responsiveness of such measures to changes in low back pain status. The purpose of this study was to assess longitudinal changes in three common measures within these clinical outcome domains over 12 months in patients with chronic low back pain.

METHODS

Study participants were recruited from the Pain Registry for Epidemiological, Clinical, and Interventional Studies and Innovation (PRECISION Pain Research Registry)[2] in Texas from April 2016 through October 2018 and followed for 12 months. Inclusion criteria consisted of being 21 to 79 years of age, having English-language proficiency, and having chronic low back pain according to the NIH case definition (pain duration of at least 3–6 months and pain frequency of at least half of the days in the past 6 months).[1] Pregnant women and institutionalized persons were excluded. The study was approved by the North Texas Institutional Review Board and all participants provided informed consent.

Participants in this observational study provided self-reported outcomes every 3 months for low back pain intensity (0–10 numerical rating scale), back-related functioning (Roland-Morris Disability Questionnaire[3]), and quality of life. The latter was a composite measure of sleep disturbance, pain interference with activities, anxiety, depression, and low energy/fatigue (SPADE cluster) derived from the Patient-Reported Outcomes Measurement Information System with 29 items (PROMIS-29).[4] Participants independently acquired their usual healthcare for low back pain, and no diagnostic tests or treatments were provided by the registry.

Repeated measures analysis of variance was used to assess outcomes across 5 time intervals (0, 3, 6, 9, and 12 months), including adjustment for age and gender. For each outcome measure, within-subjects analysis was further used to test for interaction effects involving a series of baseline demographic and clinical variables. Analyses were performed with the IBM SPSS Statistics Version 25 software, using 2-sided tests at the 0.05 level of statistical significance.

RESULTS

The characteristics of early registry participants with chronic low back pain have been reported.[5] Herein, 379 participants were enrolled during the study period, 319 (84%) were available at 12 months, and 289 (76%) reported data for all encounters. The characteristics of these 289 study participants were as follows: mean age, 54 years (SD, 11 years); women, 72%; non-White, 32%; Hispanic, 13%; history of depression, 47%; inability to do usual work for 1 month or longer because of low back pain, 37%; current use of opioids for low back pain, 35%; and history of low back surgery, 15%.

There were no significant changes over 12 months in any of the three measures (Fig. 1). Changes in each outcome measure over time were essentially unaffected by adjustment for age and gender. Of 24 tests for interaction, only one marginally significant interaction effect was observed (Table 1), involving low back pain intensity and inability to do usual work for 1 month or longer because of low back pain ($P = 0.04$).]–>

DISCUSSION

Participants with chronic low back pain in the PRECISION Pain Research Registry generally had stable clinical measures over a 12-month follow-up period, independent of baseline demographic and clinical characteristics. Strengths of this study included 12-month follow-up and use of participants from a general population, thereby providing insight into the natural history of chronic low back pain in a real-world setting wherein patients receive their healthcare from community-based providers. A study limitation was that 24% of participants did not provide complete data because of either missing quarterly encounters or attrition over time. Nevertheless, the

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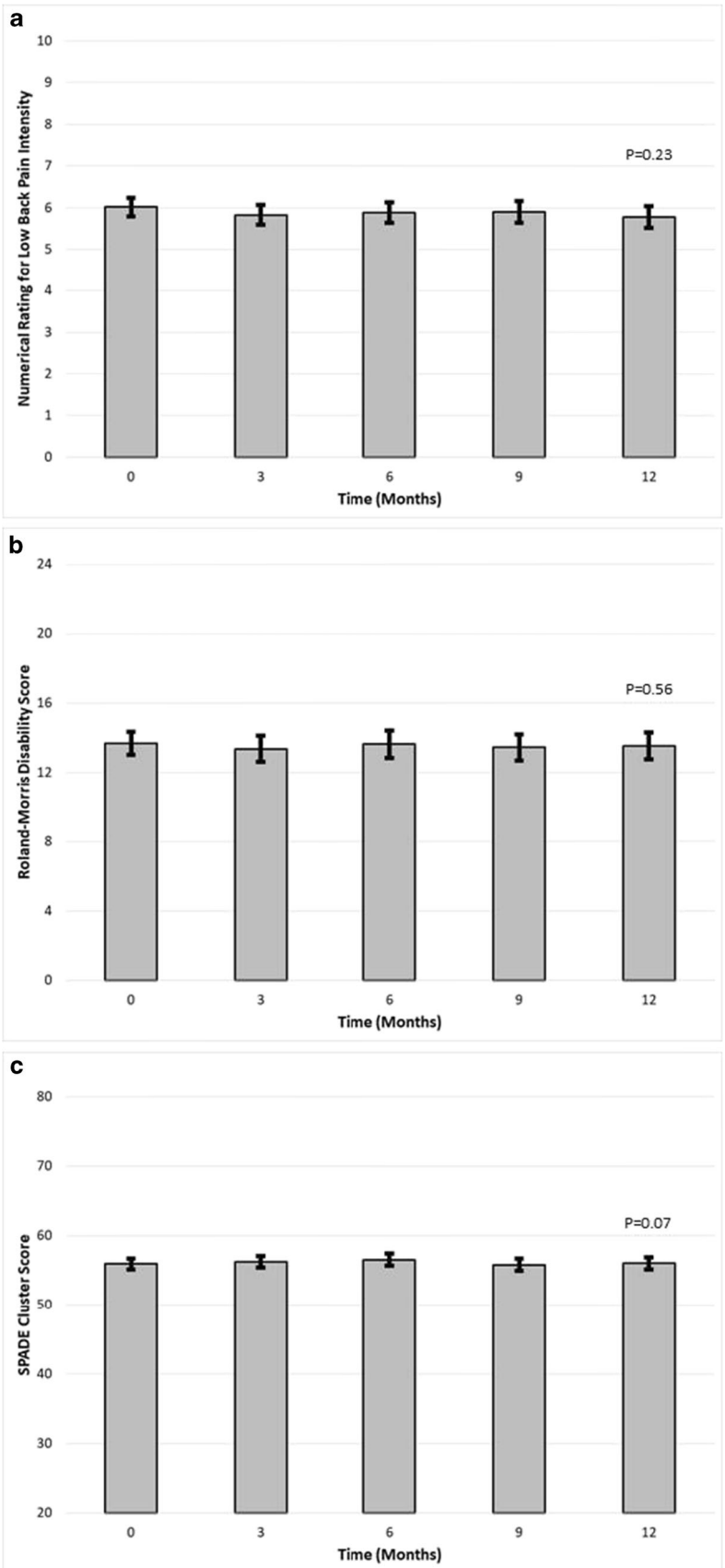

Fig. 1 Repeated measures of low back pain intensity (a), back-related functioning (b), and quality of life (c) over 12 months in 289 study participants with chronic low back pain. Back-related functioning was measured with the Roland-Morris Disability Questionnaire. Quality of life was measured with the SPADE cluster derived from the PROMIS-29. Higher scores represent worse outcomes on all measures. Error bars depict 95% confidence intervals. *P* values were computed using within-subjects repeated measures analysis of variance.

Table 1 Summary of Interaction Effects Between Clinical Outcome Measures and Participant Baseline Demographic and Clinical Characteristics ($N = 289$)

Baseline variable	Clinical outcome domain (measure)					
	Low back pain intensity (numerical rating scale)		Back-related functioning (Roland-Morris Disability score)		Quality of life (SPADE cluster score)	
	F-statistic	*P*	*F*-statistic	*P*	*F*-statistic	*P*
Age	1.03	0.39	1.02	0.40	0.43	0.79
Gender	1.02	0.40	1.32	0.26	0.11	0.98
Race	0.29	0.89	1.78	0.13	0.52	0.72
Ethnicity	0.82	0.51	1.08	0.36	0.88	0.48
History of depression	1.73	0.14	0.94	0.44	0.64	0.63
Inability to do usual work for 1 month or longer because of low back pain	2.51	0.04	1.51	0.20	0.32	0.86
Current use of opioids for low back pain	2.17	0.07	2.06	0.08	0.17	0.95
History of low back surgery	0.49	0.74	0.43	0.78	1.54	0.19

stability of longitudinal outcomes reported herein supports the utility of the numerical rating scale for low back pain intensity, Roland-Morris Disability Questionnaire, and SPADE cluster in clinical trials in which a placebo intervention for pain is either not feasible or not desirable as a design stage feature to mitigate the placebo effect and regression to the mean.[6] Thus, these three measures within the clinical outcome domains recommended by the NIH RTF may be suitable for pragmatic trials involving usual care or standard treatment arms for chronic low back pain.

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Compliance with Ethical Standards:

Conflict of Interest: *The author declares that he does not have a conflict of interest.*

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