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Construct Validity of the Promis-29 in Systemic Sclerosis: Results from the Scleroderma Patient-Centered Intervention Network (SPIN) Cohort

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SESSION INFORMATION

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Session Type: ACR Poster Session C

Session Title: Research Methodology Poster (ARHP)

Session Time: 9:00AM-11:00AM

Background/Purpose: The Patient-Reported Outcomes

Measurement Information System (PROMIS™) initiative is a cooperative research program designed to develop, evaluate, and standardize item banks to measure patient-reported outcomes across medical conditions. The PROMIS-29 measure contains 29 items, which include four items each for domains reflecting physical function, anxiety, depression, fatigue, sleep disturbance, pain interference, and ability to perform social roles, plus a single item on pain intensity. Scores are standardized with a mean of 50 and standard deviation (SD) of 10. Higher scores represent more of the domain being measured (e.g., greater sleep disturbance, greater ability to perform social roles). The purpose of this study was to examine feasibility and construct validity of the PROMIS29 in patients with systemic sclerosis (SSc) enrolled in a large multinational study.

Methods: English-speaking patients with SSc and [≥]18 years of age were enrolled in the Scleroderma Patient-centered Intervention Network (SPIN) Cohort between July 2014 and June 2015 from 19 centers across Canada, the USA and the UK. Baseline medical data are provided by the enrolling physician, and SPIN Cohort patients completed the PROMIS-29 at baseline. Floor and ceiling effects were defined as >15% of patients having the lowest or highest possible domain score, respectively. To examine convergent validity of domains,

hypotheses were formulated a-priori about the associations of domains and legacy measures. The magnitude of the correlations was interpreted as small ($|r| \leq 0.3$), moderate ($0.3 < |r| < 0.5$), or large ($|r| \geq 0.5$).

Results: In total, 473 patients were included in analyses. Mean age was 55 years (SD=11.9) and mean time since onset of the first non-Raynaud symptom was 11.8 years (SD= 8.7). Most patients were female (n=411, 86.9%) and diagnosed with limited SSc (n=277, 59.1%). Means for the PROMIS-29 domains were: function 42.8 (SD=8.7), anxiety 51.5 (SD=9.6), depression 50.9 (SD=9.2), fatigue 55.9 (SD=11.2), sleep 51.8 (SD=5.0), roles 47.5 (SD=9.6), pain interference 55.9 (SD=9.8), and pain intensity 3.7 (SD=2.7). There was a floor effect for anxiety (33.6%) and depression (37.6%), and ceiling effects for function (20.5%), roles (15.2%) and pain interference (23.7%). Most hypotheses were confirmed (7 of 9) and all were in the hypothesized direction (Table 1).

Conclusion: Results of our study support the construct validity of the PROMIS-29 in patients with SSc. Future studies should examine the influence of floor- and ceiling effects for some domains, as well as other psychometric properties of the measure.

Table 1. Hypotheses and correlations of PROMIS-29 domains and legacy instruments

PROMIS-29 domain	Legacy instrument(s)	Hypothesis for correlation ¹	Pearson correlation [95% CI]
Function	Health Assessment Questionnaire-Disability Index (HAQ-DI)	Large, negative	-0.79 [-0.82, -0.75]
	Cochin Hand Function Scale	Large, negative	-0.57 [-0.63, -0.50]
Anxiety	Brief Fear of Negative Evaluation	Moderate, positive	0.49 [0.42, 0.55]
Depression	Patient Health Questionnaire (PHQ)-8	Large, positive	0.72 [0.68, 0.76]
Fatigue	PHQ-8 item 4 (Feeling tired)	Large, positive	0.80 [0.76, 0.83]
Sleep disturbance	PHQ-8 item 3 (Trouble sleeping)	Large, positive	0.55 [0.48, 0.61]
Social roles	HAQ-DI	Moderate, negative	-0.64 [-0.69, -0.59]

Pain interference	Pain interference numeric rating scale	Large, negative	-0.82 [0.79, 0.85]
Pain intensity	Pain severity numeric rating scale	Large, positive	0.89 [0.87, 0.91]

¹The magnitude of the correlations was interpreted as small ($|r| \leq 0.3$), moderate ($0.3 < |r| < 0.5$), or large ($|r| \geq 0.5$).

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