Reliability and Validity of Patient-Reported Outcomes Measurement Information System Short Forms in Ankylosing Spondylitis

Mark C. Hwang MD,[1] Alexis Ogdie MD, MSCE,[2] Abin Puravath MD,[1] John D. Reveille MD,[1]

Key Index Terms: Ankylosing Spondylitis, Arthritis Impact Patient Reported Outcomes, Measurement Instrument, Psychometrics, Surveys

[1]Division of Rheumatology and Clinical Immunogenetics, Department of Internal Medicine, John P. and Kathrine G. McGovern Medical School, University of Texas Health Science Center at Houston (UTHealth), Houston, TX.

[2] Division of Rheumatology, Department of Medicine, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA.

Financial Support: This project was supported by the National Institute of Health PO1-AR052915. The project has not received financial support from any commercial interests. AO has served as a consultant for AbbVie, Amgen, BMS, Celgene, Corrona, Lilly, Novartis, Pfizer, and Takeda and has received grants to the University of Pennsylvania from Pfizer and Novartis. JDR has served as a consultant for Janssen, Lilly, Novartis and Pfizer. AO is supported by K23 AR063764, R01 AR072363 and the Rheumatology Research Foundation. JDR is supported by the Spondyloarthritis Association of America.

Corresponding Author: Mark C. Hwang, M.D. John P. and Kathrine G. McGovern Medical School, University of Texas Health Science Center at Houston (UTHealth), Houston, TX. – 6431 Fannin MSB.5276, Houston, TX 77030. Phone: (713) 500-6900/ Fax: (713) 500-0580. Email: Mark.C.Hwang@uth.tmc.edu

Running Head: PROMIS SF in AS

Abstract

Objective: To assess the reliability and validity of selected National Institute of Health-developed Patient-Reported Outcomes Measurement Information System (PROMIS) Short Forms (SFs) in Ankylosing Spondylitis (AS) patients across Assessment in Spondyloarthritis International Society core set and patient-identified domains.

Methods: Participants the Prospective Study of Outcomes in Ankylosing Spondylitis (PSOAS), an ongoing, prospective longitudinal observational study, completed six PROMIS SFs assessing global health, depression, fatigue, physical function, pain intensity and interference during their PSOAS visits from September 2017-January 2019. Test-retest reliability and internal consistency was assessed using Intraclass correlation coefficients and Cronbach's alpha, respectively. PROMIS SFs were compared to legacy measures collected. Construct validity was evaluated through examination of score distributions, floor effects and through examination of the Spearman's correlation coefficients between PROMIS measures and existing legacy AS measures. Discriminant validity was tested across Ankylosing Spondylitis Disease Activity Score (ASDAS) groups.

Results: Participants (N=119) were mostly male (69%), white (81%) with a mean(SD) age of 51(±15) years. Legacy measures demonstrated floor effects that were not present in PROMIS SFs. Good test-retest reliability ($r>0.8$) and excellent internal consistency ($\alpha>0.9$) was noted in the PROMIS SFs. The six PROMIS SFs correlated moderately to strongly (rho 0.68[Depression]-0.87[Physical Function]) with appropriate legacy measures. PROMIS scores measures worsened significantly ($p<.05$) with higher ASDAS groups.

Conclusion: This study supports the reliability and construct validity of PROMIS SFs to assess AS symptoms from a single-center sample of AS patients. Further research is needed to test responsiveness, feasibility/resource burden, and different cultural/societal contexts for AS patients.

Significance and Innovation

- This is the first study to examine the psychometric performance of the Patient-Reported Outcomes Measurement Information System (PROMIS) in patients with ankylosing spondylitis.
- Results provide preliminary data in the reliability and validity of the PROMIS SFs in AS.
- PROMIS SFs demonstrated a more normal distribution compared to legacy measures in the physical domains studied.

Patient-reported outcomes (PROs) are an important component of rheumatologic care and research. They have increased patient participation and yielded valuable information on treatment efficacy and quality of life that is pertinent to the management of patients with these complex, chronic diseases(1, 2). Subsets of PROs have also been established as core outcome domains for many rheumatic diseases to evaluate therapeutic efficacy(3).

Ankylosing spondylitis (AS) is a disease characterized by inflammatory back pain and radiographic disease of the axial spine with an estimated prevalence of 0.2 to 0.5% in the US population(4). Clinicians have widely adopted the use of PROs as important tools in AS management. In fact, PROs comprise the largest share of the primary outcome in randomized controlled trials in AS(5) The Assessment of Spondyloarthritis International Society/Outcome Measures in Rheumatology (ASAS/OMERACT) international groups have established three independent core sets of domains used to measure outcomes: disease-controlling antirheumatic treatment, symptom-modifying antirheumatic drugs and physical therapy, and one for clinical record-keeping(6). All three core sets include the domains of fatigue, function, pain, patient global assessment and stiffness. These domains are important both from a research and clinical care level in AS.

Universal (or “generic”) PROs measures represent an opportunity to compare disease burden and treatment impact across different chronic conditions using a common metric(7). The National Institutes of Health (NIH)-funded Patient Reported Outcomes Measurement Information System (PROMIS) incorporates both adult and pediatric PROs in physical, mental and social health domains across a wide variety of chronic diseases and conditions as well as general population controls, potentially allowing for this type of comparison(8). The physical

health domains captured by PROMIS are particularly relevant in rheumatology(9). The use of item response testing (IRT) methodology yielded computer adaptive tests (CAT), static profiles, and short forms (SFs) PROMIS instruments that are publicly available for use. Investigators continue to explore how PROMIS measures can be incorporated into different aspects of medical research and care(10).

While the ASAS/OMERACT PRO measures are vital in the assessment of AS, the IRT methodology used in PROMIS potentially reduces redundancy, increases sensitivity by avoiding floor/ceiling effects, and decreases survey-burden with its adaptive design. Additionally, the publicly available online data collection system (Assessment Center, www.assessmentcenter.net) may furthermore decrease barriers to clinical research in AS including accessibility and ease of use. The purpose of this study is to examine the reliability and validity of PROMIS SFs in AS patients.

Materials and Methods:

Patients

Subjects were recruited from a single center (UTHealth) among patients currently enrolled in the Prospective Study of Ankylosing Spondylitis (PSOAS) observational cohort. All clinic patients at the UTHealth study-site that met modified New York Classification Criteria for AS, ≥18 years of age, and were fluent in English were eligible for participation. PSOAS is a multicenter observational study initiated in 2003 with continued enrollment encompassing five sites: Cedars-Sinai Medical Center, Los Angeles, CA; the National Institutes of Health Clinical Center, Bethesda, MD; the McGovern Medical School at the University of Texas Health Science Center at Houston (UTHealth), Houston, TX; the University of California, San Francisco, and the

Princess Alexandra Hospital in Brisbane, Australia. The research followed the Helsinki declaration, was approved by the University of Texas Institutional Review Board (HSC-MS-07-0022), and each participating subject reviewed and signed an informed consent form.

Procedures

Patients were contacted by phone, at their clinic visit, or at their study visit about participation and details regarding this ancillary study. After providing written informed consent, coordinators provided paper questionnaire packets in person and/or via email for printing. A subset of patients was consecutively approached and asked to complete the same PROMIS SFs >48 hours later to assess test-retest reliability from May to November 2018. We used data from a single patient visit per patient.

Patient Reported Outcomes

Focus groups of AS patients (3 groups of 5 patients) were asked if the domains listed in the ASAS/OMERACT were important for their disease and if there were any additional domains they felt needed to be measured. Five academic rheumatologists at UTHealth involved in AS research and patient care were individually asked the same questions. After soliciting these opinions, we found that the core domains were well accepted among patients and rheumatologists. Mental health, specifically depression, was an important domain that was the most noted domain not covered in the ASAS/OMERACT core set.

PROs that are routinely collected in the PSOAS cohort include Patient Global assessment (0-100 Numeric Rating Scale [NRS]), Patient Pain assessment(0-100 NRS), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Ankylosing Spondylitis Disease Activity Score-CRP (ASDAS), Center for Epidemiologic Studies

Depression Scale (CES-D)(11-14). The BASDAI consists of six question measured on a 0-10 scale covering 5 major symptoms of AS: fatigue, spinal pain, arthralgias/arthritis, enthesitis, and morning stiffness(11). Additionally, *Calin et al.* developed the BASFI, a ten-question index measured on the mean of 0-10 scales focused on functional AS anatomical limitations(12). The ASDAS is a newer disease activity designed specifically for Ankylosing Spondylitis demonstrating high discriminant capacity and incorporates acute phase reactions (e.g. erythrocyte sedimentation rate or c-reactive protein)(13). The CES-D is a 20-item questionnaire measuring depressive symptom severity(14). These measures were termed "legacy" measures and served as comparators for the PROMIS measures addressing similar constructs.

As part of the NIH Roadmap initiative for 21st century for medical research, the multi-center cooperative group referred to as PROMIS was formed. This group utilized modern advances in computer technology and item-response theory to create free-to-use measures for physical, mental, and social health domains (15). Among the ways to administer PROMIS measures (on paper, by computer or mobile application), we chose SFs distributed in paper packets for ease of use in a clinical setting. Scoring manuals for PROMIS measures (www.assessmentcenter.net/Manuals.aspx) outline the SF development, report psychometric properties for each instrument in their study population, and described how to identify PROMIS T-scores based on short form raw summed item scores. We reported PROMIS T-scores for all SFs. PROMIS SF Versions v1.0/1.1 (assessmentcenter.net) were administered for: Emotional Distress-Depression, Fatigue, Global Health, Pain Intensity, Pain Interference and Physical Function and ranged from 3 to 12 questions per form (Supplemental Figure 1). For the PROMIS Global v1.1 Short Form we reported the physical summary score. These domains were selected

based on patient input, expert rheumatologist input and published Assessment of Spondyloarthritis (ASAS)-Outcome Measures in Rheumatology (OMERACT) core set for clinical record keeping (6). Higher PROMIS scores represent more of the measured trait, so interpretation of directionality varied if the domain was a positive trait (higher scores better) versus symptom (higher scores indicate more severe symptoms). Time to complete was self-reported by patients upon completion of the PRO packet. We additionally solicited patient feedback regarding the PROMIS questionnaires in terms of how well they addressed the measured domains and if any important aspects of their disease were not being addressed through open-ended critiques.

Covariates

Socio-demographic information was drawn from the patients' data extracted from the PSOAS cohort and included age, gender, race/ethnicity, education, smoking, comorbidities, work status, and AS duration. Medication use, comorbidities, and serum inflammatory markers (e.g. C-reactive protein [CRP], erythrocyte sedimentation rate) was also recorded at each visit in addition to radiographs of the hips, cervical and lumbar spine (the latter, measured by the modified Stoke Ankylosing Spondylitis Scoring Scale), obtained at two-year intervals over the course of follow up.

Statistical Analysis

Central tendency and distribution were calculated by mean(SD) or median(IQR) for continuous normal vs. non-normal data, respectively. Frequencies and percentages were descriptively reported for categorical variables. We examined histograms, skewness and kurtosis statistics to assess normality(16). For skewness and kurtosis we look at their z-scores by divided their

values over their standard error, with values >|1.96| considered significant. Spearman's correlation was used to examine PROMIS scores against legacy PROs for similar domains. Kruskal-Wallis H-Test with Bonferroni correction for pair-wise comparisons was used to compare PROMIS and legacy PRO domains stratified by ASDAS group levels. Intraclass correlation and Cronbach's alpha were used to assess test-retest reliability and internal consistency, addressing reliability; a correlation coefficient or alpha coefficient >|0.7| was considered acceptable. We hypothesized *a priori* that there would be moderate to strong correlation (rho >|0.6|) between the PROMIS measures and the target legacy measures. All analyses were done with IBM SPSS version 24.

Results

Patient Characteristics

A total of 119 patients were enrolled and completed the surveys between September 2017 and January 2019. 24 of the 88 patients (27.3%) from May 2018 through November 2018 who completed the retest packet in addition. This sample included a diverse spectrum of AS characteristics (Table 1.) Patient were mostly male (69%), white (81%) with a mean (SD) age of 51 (15) years of age. All patients met modified New York Criteria for Ankylosing Spondylitis with a mean symptom duration of 25(±13) years. In those who had available CRP lab values (90/119, 76%), over half (64%) had inactive or moderate disease by ASDAS.

Distributions of PROs

PROMIS and legacy scores are shown in Table 2. No significant kurtosis was noted in the legacy or PROMIS questionnaires. All Legacy PROs were moderately to highly positively skewed (0.54 to 1.00) with the Patient Global, Patient Pain, BASFI, and CESD significantly skewed (p<.05).

Many of the instruments, demonstrated floor effects with the proportion of patients at the lowest potential score (e.g. lowest possible score) in each of the legacy measures ranging from 5-17%: Global Health NRS (17%), CES-D (9%), BASDAI-Fatigue (5%), Pain (14%) and BASFI (11%). The PROMIS instruments showed a more normal distribution compared to legacy measures in physical domains (Figure 1, Supplemental Figure 2.) with PROMIS Global, Fatigue, Pain Interference, Pain Intensity, Physical Function approximately symmetric (-0.1 to 0.39 skew, $p>.05$). However, PROMIS Emotional Distress-Depression had positive skew (1.01, $p<.05$) with significant floor effect (e.g. 54% with lowest possible value PROMIS-ED) (Supplemental Figure 2). Floor effects for the rest of the PROMIS measures otherwise ranged from 1-31%: Global (1%), Fatigue (9%), Pain Interference (31%), Pain Intensity (11%), Physical Function (1%). Among a subset that were sampled for time of completion, 35/41 (85%) stated that overall it was <15 minutes to complete their PROMIS SF packets. Fourteen of the 119 (12%) patients raised potential concerns regarding the PROMIS SF addressing their disease.

Reliability

Test-retest reliability was tested among the 24 participants. The median (IQR) time between the two measures was 1 day (IQR 1, 2). Correlations between the individual tests' two scores ranged from 0.80 (Pain Interference) to 0.98 (Physical Function). We also examined internal consistency using Cronbach's Alpha. We found excellent consistency within the individual scales ranging from 0.91 (Global) to 0.98 (Pain interference).

Construct validity: Convergent Validity and Known Groups Validity with Legacy Measures

PROMIS Global Health, Physical Function and Pain Intensity had very strong correlation (rho value >0.84, $p<.01$) with corresponding legacy measures (Global NRS, BASFI, and Pain NRS

respectively). (Table 3). PROMIS Pain Interference and Fatigue showed strong correlation (rho >0.7, p<.01) with corresponding legacy measures (Pain NRS and BASDAI-Fatigue respectively). The weakest correlation was seen with PROMIS Emotional Distress-Depression which had moderate correlation (rho=0.68, p<.01) with CES-D.

In general, PROMIS scores measures worsened significantly (p<.05) with increased disease activity as defined by ASDAS categories ranging from inactive disease (ASDAS <1.3) to high-very high disease activity (ASDAS ≥2.1) in the domains of: Global, Fatigue, Pain Intensity, Pain Interference, Depression and Physical Function (Table 4). In pairwise comparisons, PROMIS Global and Physical Function distinguished inactive, moderate, and high-very high ASDAS-defined disease activity. PROMIS Fatigue, Pain Intensity, Pain Interference were able to distinguish ASDAS inactive and moderate from high-very high disease activity. We observed these same patterns among the legacy measures (Patient Global, Pain, BASFI, BASDAI-Fatigue) that addressed physical domains. PROMIS Emotional Distress-Depression measure was unable to distinguish across ASDAS-defined disease activity unlike CESD that could distinguish high-very high disease compared to inactive disease.

Discussion

To the best of our knowledge, this study is the first to examine the reliability, construct validity of PROMIS instruments in AS patients in the context of ongoing clinical care. We selected PROMIS SFs from a patient & clinician perspective based on patient and physician input as well as review of the ASAS/OMERACT clinical record keeping domains. Among the six domains we studied (e.g. Depression, Fatigue, Global Health, Physical Function, Pain Intensity & Interference), five of the six showed at least strong correlation (rho>|0.7|) with the appropriate

legacy AS measure. Additionally, in the physical domains of Global Health and Physical Function PROMIS measures were able to discriminate inactive, moderate and high-very high ASDAS activity groups. Similarly, in the other physical domains (i.e. Pain Intensity, Pain Interference, Fatigue) the PROMIS measures could discriminate high-high disease vs. low-moderate disease activity groups. In depression, the only mental health domain, PROMIS Depression could not distinguish across disease activity levels suggesting that depressive symptoms as defined in this SF may not be disease-related. A majority of patients also found these forms to take <15 minutes of time to complete. These findings support the feasibility, reliability and construct validity of PROMIS SFs when assessing physical domains in AS outcomes.

PROMIS instruments have been evaluated across multiple physical, mental and social health domains in other rheumatic diseases including juvenile idiopathic arthritis, osteoarthritis (OA), psoriatic arthritis, rheumatoid arthritis (RA) systemic lupus erythematosus (SLE), systemic sclerosis and vasculitis(17-23). While a majority of these studies have focused on PROMIS CAT, to date PROMIS SF have been studied in OA, RA and SLE in similar fashion(24-27). PROMIS instruments have also been studied in treatment response(28). In addition, PROMIS measures have also correlated with objective measures. For example, *Mahieu et al.* demonstrated reliability and construct validity in PROMIS Fatigue with accelerometer-based measures of physical activity in SLE patients(29). This may suggest the potential cross-disease nature of these universal PROs.

Strengths of this study included use of a well-characterized cohort reflective of AS patients in the United States with AS legacy measures collected routinely at each study visit. All patients met modified New York Criteria for Ankylosing Spondylitis, creating a homogenous patient

sample from a radiographic perspective. We evaluated the performance of PROMIS measures within the context of usual care.

Our study had limitations. The highly educated, largely Caucasian demographics of our patient sample may impact generalizability. Floor effects noted for the PROMIS Depression SF and CESD may have been due to the low depression rate in our sample. Furthermore, by only including patients who met modified New York Criteria for AS we excluded patients on the disease spectrum with non-radiographic axial spondyloarthritis (nr-AxSpA). Thus, our study may not be generalizable to nr-AxSpA patient populations. Due to potential rapid changes in underlying disease activity with medications, the 48-hour type window was chosen to assess test-retest which may also artificially elevate the correlation observed. For both test-retest and time of completion, we acknowledge potential participation bias of those who volunteered this information. We also did not study responsiveness of the PROMIS instruments in this study and limited our study to English speaking patients only. Furthermore, while the use of SF is feasible in all potential settings given its paper format, we did not study the CAT or profile PROMIS instruments.

Our study offers preliminary data in the study of PROMIS instruments in AS. Further study is required to see, separately, if the PROMIS CAT can reduce redundancy, increase sensitivity by avoiding floor/ceiling effects, or decrease survey-burden with its adaptive design in AS patients. Future PROMIS SF studies in AS could include translations of PROMIS instruments given the dynamic demographics seen in the US population. Furthermore, longitudinal studies are required to study the responsiveness of PROMIS SFs in AS patients.

In conclusion, this study offers evidence supporting the feasibility as well as the reliability and construct validity of six PROMIS instruments in AS clinical care. Additionally, our study demonstrates the impact and disease burden of AS across the domains studied relative to the general population, facilitated by comparing AS scores to population normative values. As PROMIS measures are more widely used in clinical trials and US clinical care, the construct validity of these measures in AxSpA will be increasingly relevant. Future work will examine the longitudinal construct validity and discrimination of these instruments in treatment initiation scenarios and continue to elucidate how PROMIS instruments can be used to understand the impact of AS in different cultural and societal contexts.

Acknowledgements

The authors are deeply grateful to the patients and their families for their participation and support in this study, and to the staff at the Division of Rheumatology and Clinical Immunogenetics, Center for Clinical Research and Evidence-Based Medicine, and Center for Clinical and Translational Sciences at UTHealth. We also like to thank the PSOAS investigators for their continued collaboration.

Author Contributions

Conceived and designed the experiments: MCH, AO, AP, JDR

Acquisition of data: MCH, AP, JDR

Analyzed and interpretation of the data: MCH, AO, JDR

Drafting of Manuscript: MCH, AO, JDR

Critical review of the manuscript and final approval of submission: MCH, AO, AP, JDR

References

1. Minnock P, Kirwan J, Bresnihan B. Fatigue is a reliable, sensitive and unique outcome measure in rheumatoid arthritis. Rheumatology 2009;48:1533-6.
2. Wells G, Li T, Maxwell L, Maclean R, Tugwell P. Responsiveness of patient reported outcomes including fatigue, sleep quality, activity limitation, and quality of life following treatment with abatacept for rheumatoid arthritis. Ann Rheum Dis 2008;67:260-5.
3. van Tuyl LH, Boers M. Patient-reported outcomes in core domain sets for rheumatic diseases. Nat Rev Rheumatol 2015;11:705-12.
4. Stolwijk C, van Onna M, Boonen A, van Tubergen A. Global prevalence of spondyloarthritis: A systematic review and meta-regression analysis. Arthritis Care Res 2016;68:1320-31.
5. van der Heijde D, Dougados M, Davis J, Weisman MH, Maksymowych W, Braun J, et al. Assessment in ankylosing spondylitis international working group/spondylitis association of america recommendations for conducting clinical trials in ankylosing spondylitis. Arthritis Rheum 2005;52:386-94.
6. Sieper J, Rudwaleit M, Baraliakos X, Brandt J, Braun J, Burgos-Vargas R, et al. The assessment of spondyloarthritis international society (asas) handbook: A guide to assess spondyloarthritis. Ann Rheum Dis 2009;68 Suppl 2:ii1-44.
7. Universal health outcome measures for older persons with multiple chronic conditions. J Am Geriatr Soc 2012;60:2333-41.
8. Ader DN. Developing the patient-reported outcomes measurement information system (promis). Med Care 2007;45:S1-S2.
9. Khanna D, Krishnan E, Dewitt EM, Khanna PP, Spiegel B, Hays RD. The future of measuring patient-reported outcomes in rheumatology: Patient-reported outcomes measurement information system (promis). Arthritis Care Res 2011;63 Suppl 11:S486-90.
10. Baumhauer JF. Patient-reported outcomes - are they living up to their potential? N Engl J Med 2017;377:6-9.
11. Garrett S, Jenkinson T, Kennedy LG, Whitelock H, Gaisford P, Calin A. A new approach to defining disease status in ankylosing spondylitis: The bath ankylosing spondylitis disease activity index. J Rheumatol 1994;21:2286-91.
12. Calin A, Garrett S, Whitelock H, Kennedy LG, O'Hea J, Mallorie P, et al. A new approach to defining functional ability in ankylosing spondylitis: The development of the bath ankylosing spondylitis functional index. J Rheumatol 1994;21:2281-5.
13. Radloff LS. The ces-d scale: A self-report depression scale for research in the general population. Appl Psychol Meas 1977;1:385-401.
14. Machado P, Landewé R, Lie E, Kvien TK, Braun J, Baker D, et al. Ankylosing spondylitis disease activity score (asdas): Defining cut-off values for disease activity states and improvement scores. Ann Rheum Dis 2011;70:47-53.
15. Cella D, Yount S, Rothrock N, Gershon R, Cook K, Reeve B, et al. The patient-reported outcomes measurement information system (promis): Progress of an nih roadmap cooperative group during its first two years. Med Care 2007;45:S3-S11.
16. Bliss CI. Statistics in biology; statistical methods for research in the natural sciences. New York: McGraw-Hill; 1967.
17. Brandon TG, Becker BD, Bevans KB, Weiss PF. Patient-reported outcomes measurement information system tools for collecting patient-reported outcomes in children with juvenile arthritis. Arthritis Care Res 2017;69:393-402.

18. Broderick JE, Schneider S, Junghaenel DU, Schwartz JE, Stone AA. Validity and reliability of patient-reported outcomes measurement information system instruments in osteoarthritis. Arthritis Care Res 2013;65:1625-33.
19. Orbai A-M, Mease PJ, de Wit M, Kalyoncu U, Campbell W, Tillett W, et al. Report of the grappa-omeract psoriatic arthritis working group from the grappa 2015 annual meeting. J Rheumatol 2016;43:965-9.
20. Bartlett SJ, Orbai A-M, Duncan T, DeLeon E, Ruffing V, Clegg-Smith K, et al. Reliability and validity of selected promis measures in people with rheumatoid arthritis. PLoS One 2015;10:e0138543.
21. Kasturi S, Szymonifka J, Burket JC, Berman JR, Kirou KA, Levine AB, et al. Validity and reliability of patient reported outcomes measurement information system computerized adaptive tests in systemic lupus erythematosus. J Rheumatol 2017;44:1024-31.
22. Khanna D, Maranian P, Rothrock N, Cella D, Gershon R, Khanna PP, et al. Feasibility and construct validity of promis and "legacy" instruments in an academic scleroderma clinic. Value Health 2012;15:128-34.
23. Robson JC, Tomasson G, Milman N, Ashdown S, Boonen A, Casey GC, et al. Omeract endorsement of patient-reported outcome instruments in antineutrophil cytoplasmic antibody-associated vasculitis. J Rheumatol 2017;44:1529-35.
24. Driban JB, Morgan N, Price LL, Cook KF, Wang C. Patient-reported outcomes measurement information system (promis) instruments among individuals with symptomatic knee osteoarthritis: A cross-sectional study of floor/ceiling effects and construct validity. BMC Musculoskelet Disord 2015;16:253.
25. Bartlett SJ, Gutierrez AK, Butanis A, Bykerk VP, Curtis JR, Ginsberg S, et al. Combining online and in-person methods to evaluate the content validity of promis fatigue short forms in rheumatoid arthritis. Qual Life Res 2018;27:2443-51.
26. Kasturi S, Szymonifka J, Burket JC, Berman JR, Kirou KA, Levine AB, et al. Feasibility, validity, and reliability of the 10-item patient reported outcomes measurement information system global health short form in outpatients with systemic lupus erythematosus. J Rheumatol 2018;45:397-404.
27. Katz P, Yazdany J, Trupin L, Rush S, Helmick CG, Murphy LB, et al. Psychometric evaluation of the nih patient-reported outcomes measurement information system (promis((r))) in a multi-racial, multi-ethnic systemic lupus erythematosus (sle) cohort. Arthritis Care Res 2018.
28. Wohlfahrt A, Bingham CO, 3rd, Marder W, Phillips K, Bolster MB, Moreland LW, et al. Responsiveness of patient reported outcomes measurement information system (promis) measures in ra patients starting or switching a dmard. Arthritis Care Res 2018.
29. Mahieu MA, Ahn GE, Chmiel JS, Dunlop DD, Helenowski IB, Semanik P, et al. Fatigue, patient reported outcomes, and objective measurement of physical activity in systemic lupus erythematosus. Lupus 2016;25:1190-9.

Table 1. Participant characteristics (N=119)

Characteristic	N	Value (%)
Age (Mean SD; years)	119	50.85 ± 14.77
Male Gender	119	82 (69%)
Race	119	
White		96 (81%)
Other		23 (19%)
Education	119	
High School		16 (13%)
College		103 (87%)
Employment status	119	
Full time		76 (64%)
Not Working		31 (27%)
Disabled		11 (9%)
Self-Reported Depression	119	16 (13%)
AS Symptom Duration (Mean SD; years)	119	25.47 ± 13.32
ASDAS *	90	
Inactive		26 (31%)
Moderate		28 (33%)
High-Very High		30 (36%)
Biologic DMARD usage †	110	66 (56%)
Last mSASSS (Median [IQR])‡	85	4 (0-34)

* Missing = 29 due to lack of CRP labs.

† Missing = 9 due to incomplete medication list

‡ Missing = 34 due to incomplete radiographs

Table 2. PROMIS and legacy measure scores in AS patients

	N	Mean	Median	Std. Deviation	Range	Minimum	Maximum	Test-retest ICC (95% CI)*	Cronbach's alpha (95% CI)
Patient Global									
PROMIS Global	119	45.62	44.90	8.90	44.20	23.50	67.70	.898 (.763, .958)	.910 (.884, .932)
Global VAS (NRS)	115	29.13	20.00	25.15	100.00	0.00	100.00		
Depression									
PROMIS Emotional Distress -Depression	118	45.28	38.20	8.48	31.50	38.20	69.70	.859 (.699, .938)	.936 (.917, .952)
Center for Epidemiologic Studies-Depression	109	11.00	9.00	8.67	39.00	0.00	39.00		
Fatigue									
PROMIS Fatigue	118	51.07	49.80	10.46	44.70	33.10	77.80	.901 (.788, .955)	.972 (.964, .979)
Bath Ankylosing Spondylitis Disease Activity Index-Fatigue	115	4.12	3.00	2.78	10.00	0.00	10.00		
Pain									
PROMIS Pain Intensity	119	45.74	46.30	8.89	36.70	30.70	67.40	.871 (.729, .941)	.912 (.881, .937)
PROMIS Pain Interference	119	52.23	53.20	9.91	36.30	40.70	77.00	.814 (.616, .915)	.978 (.972, .984)
Pain VAS (NRS)	115	32.17	20.00	28.18	100.00	0.00	100.00		
Physical Function									
PROMIS Physical Function	112	46.56	45.20	9.80	41.00	25.10	66.10	.957 (.905, .981)	.922 (.899, .942)
Bath Ankylosing Spondylitis Functional Index	113	3.06	2.40	2.63	9.40	0.00	9.40		

*N=25

Table 3. Correlations between PROMIS and legacy measures in AS patients

	Global VAS (NRS)	CES-D	BASDAI-Fatigue	Pain VAS (NRS)	Bath Ankylosing Spondylitis Functional Index
PROMIS Global	-.864**	--------	--------	--------	--------
PROMIS Emotional Distress - Depression	--------	.711**	--------	--------	--------
PROMIS Fatigue	--------	--------	.708**	--------	--------
PROMIS Pain Intensity	--------	--------	--------	.856**	--------
PROMIS Pain Interference	--------	--------	--------	.746**	--------
PROMIS Physical Function	--------	--------	--------	--------	-.872**

*p<.05, **p<.01

Table 4. PROMIS and legacy measures by ASDAS disease activity levels

	Inactive Disease (n = 25)		Moderate Disease Activity (n = 30)		High Disease Activity (n = 35)	
	Mean	SD	Mean	SD	Mean	SD
Patient Global						
PROMIS Global	53.46_a	5.73	47.31_b	6.19	38.39_c	6.17
Global VAS (NRS)	6.80_a	8.02	22.33_b	14.07	49.14_c	23.98
Depression						
PROMIS Emotional Distress - Depression*	41.71_a	6.26	46.02_a	9.72	46.95_a	8.17
Center for Epidemiologic Studies-Depression	6.63_a	5.28	9.11_a	8.49	13.94_b	8.27
Fatigue						
PROMIS Fatigue	44.44_a	8.09	47.89_a	9.15	57.43_b	10.75
Bath Ankylosing Spondylitis Disease Activity Index-Fatigue	1.60_a	1.38	3.30_a	2.04	6.63_b	2.26
Pain						
PROMIS Pain Intensity	38.56_a	5.95	42.31_a	6.17	52.93_b	6.54
PROMIS Pain Interference	44.77_a	6.50	47.88_a	7.01	60.53_b	6.77
Pain VAS (NRS)	8.40_a	8.00	18.67_a	15.92	58.86_b	21.93
Physical Function						
PROMIS Physical Function	54.67_a	8.60	46.31_b	7.34	40.68_c	6.90
Bath Ankylosing Spondylitis Functional Index	0.97_a	1.02	2.55_b	1.73	4.99_c	2.65

Note: Values in the same row not sharing the same subscript are significantly different at adjusted significance of $p<.05$, SD= Standard deviation.
*$p>.05$ in PROMIS-Depression

FIGURE 1.

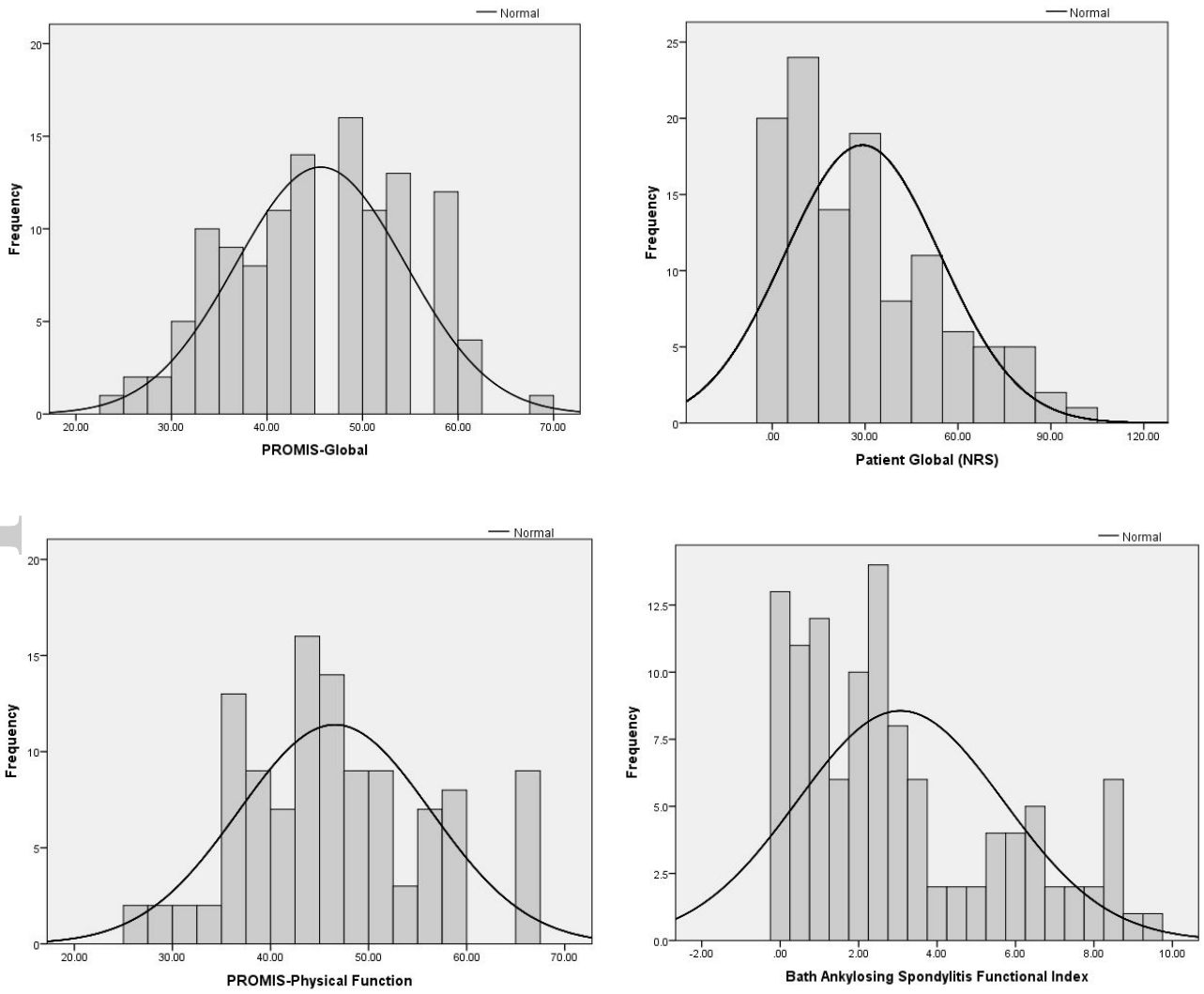

Figure 1. Distribution of select PROMIS *(on left)* and legacy scores *(on right)* in Ankylosing Spondylitis patients (N = 119).