PSYCHOMETRIC PERFOMANCE OF A 9-ITEM PROMIS UPPER EXTREMITY INSTRUMENT FOR PHYSICAL FUNCTION AMONG INDIVIDUALS WITH AMPUTATION

Dwiesha L. England[1], MS, Taavy A. Miller[1], MSPO, Phillip M. Stevens, Med[1,2], Shane R. Wurdeman, PhD[1,3]

[1]Department of Clinical and Scientific Affairs, Hanger Clinic, Austin, TX, USA,
[2]School of Medicine, University of Utah, Salt Lake City, UT, USA
[3]Department of Biomechanics, University of Nebraska, Omaha, NE, USA

ABSTRACT

The use of outcome measures are often a policy-driven requirement when assessing the efficacy of clinical care in several patient populations including prosthesis users. A recent review of upper extremity instruments described the PROMIS measures as a "potential improvement to current practice"[1]. Thus, the PROMIS-9 UE was developed from the PROMIS UE item bank to assess psychometric performance among individuals with UE amputation. Performance testing was achieved by evaluating structural and known-groups validity, reliability and differential item functioning (DIF) among participants. To be structurally valid, the assumptions of unidimensionality (one dominant factor obtained), local independence (i.e. all LD $\chi 2<10$), monotonicity (scalable coefficient for the full scale equates to 0.57) and good model fit (p-values>0.006 for all items) were confirmed. The graded response model results, for the item difficulty parameter, revealed that the nine items were covering low to moderate levels of physical function. Known-groups analysis demonstrated that prosthesis users had significantly higher levels of physical function compared to non-user (p=0.039). Lastly, the PROMIS-9 UE had adequate item response theory (IRT) reliability, 0.9, and no age DIF were found. Although there is a need for more challenging questions, the PROMIS-9 UE psychometrically performed well supporting its continued utilization for individuals with low to moderate levels of physical functioning.

INTRODUCTION

Prominently utilized upper extremity (UE) physical function instruments, that predate the establishment of the PROMIS physical function UE item bank, report having limitations such as ceiling effects, non-unidimensional factor structure, or lengthiness [2], [3]. To overcome these limitations, the PROMIS group developed fixed length short forms and computer adaptive test from validated item banks across several domains including pain, anxiety and physical function. The PROMIS v2.0 UE physical function item bank allows [4] content experts to create a customized short form by selecting items clinically relevant to their targeted population and subsequently test its performance in a clinical setting. A recent study found that the PROMIS UE item bank had good psychometric properties such as adequate structural validity, sufficient differential item function and good reliability among individuals with upper limb complaints [5]. To build on this body of evidence, it was hypothesized that a customized 9-item measure, PROMIS-9 UE, chosen from the PROMIS v2.0 UE item bank, will also perform well within a specified population of individuals with upper extremity amputation.

METHOD

Study design

Patients with UE amputation across the United States completed the PROMIS-9 UE measure and demographic data during a routine visit with their prosthetist. Retrospective chart review of cross-sectional data was used to determine the psychometric performance of the PROMIS-9 UE.

Subjects

A database containing 269 patients were reviewed. To be included in the analysis, individuals had to be 18 years and older, have received an upper extremity amputation and have completed a PROMIS-9 UE questionnaire.

Statistical Analysis

All statistical analyses were performed using IRTPRO (version 4.1) and R (version 3.6.1). Patients' demographic data were described using sample means, standard deviations and percent proportions.

The structural validity of the PROMIS-9 UE was assessed by evaluating three IRT assumptions before fitting a graded response model. These assumptions include: 1) unidimensionality, 2) local independence and 3) monotonicity [6]. Unidimensionality is define as the instrument ability to measure one domain, for this current study, physical function. Exploratory factor analysis was used to determine if the PROMIS-9 UE had one factor or a dominant first factor. Local independence dictates that there should be no association between items, after controlling for the measured trait. This was verified using IRTPRO's local dependence chi-square statistics (LD $\chi 2$). If any LD $\chi 2$ value exceeded 10 then local independence was violated [7]. Lastly, monotonicity occurred when the probability of selecting a higher response category increases with the levels of the measured trait. The R-package Mokken (version 2.8.11) was used to verify whether monotonicity was held for the PROMIS-9 UE instrument. If all three assumptions were met, results obtained from the logistic graded response model with S-$\chi 2$ can be interpreted. From the model, p-values less than 0.006 are suggestive of poor model fit and a wide range for the item difficulty parameter is suggestive of good coverage.

Known-groups Analysis

Known-groups analysis was used to assess differences in physical functioning T-scores for prosthesis users versus non-prosthesis users. This was carried out using an independent samples t-test. T-scores were obtained from HealthMeasures.net scoring service.

DIF and Reliability

When the influence of age, gender or education status impacts an individual's response to an item category, then DIF has occurred. Items flagged for DIF can add noise to the instrument and some studies recommended that non-relevant items with significant DIF be excluded. DIF was assess using IRTPRO (version 4.1). Reliability evaluates the instrument's capabilities to precisely measure the domain of physical function. Traditional Cronbach's alpha gives the reliability for the entire instrument while the IRTPRO reliability gives the precision for individual values of T-score within the scale.

RESULTS

After removing patients with incomplete PROMIS-9 UE data, a convenience sample of 239 individuals was retained in the final analysis. Over 70% of the population were male, 45% were transradial and 63 % were prosthesis users at the time of the survey (table 1).

Table 1: Patients' Characteristics

	Count (n)	%
Total Sample	239	100
Gender, male	170	71
Education, college degree	143	60
Employed, yes	106	44
Acquired amputation, yes	171	72
Amputation Level		
Transhumeral/elbow	40	17
Transradial/wrist	107	45
Prosthesis user, yes	150	63
	Mean	**SD**
Age of participants (yrs)	48	16
Use of prosthesis (hrs/day)	9	5.3
PROMIS-9 UE T-scores	29.6	9.8

Structural validity

Unidimensionality analysis revealed that physical function was a dominant factor for the PROMIS-9 UE. None of the items violated the assumption of local independence as all LD$\chi 2$ values had a magnitude less than 10. Also, the assumption of monotonicity was met because the scalability coefficient for the full scale (0.565) exceeded the minimum value of 0.5. Model results indicated that none of the items were poorly fitted ($p > 0.006$). The item difficulty level of the scale ranged from -1.44 to 1.34 suggesting low to moderate coverage for physical function

Known Group Validity

As expected, prosthesis users had significantly higher t-scores than non-prosthesis users ($p=0.039$).

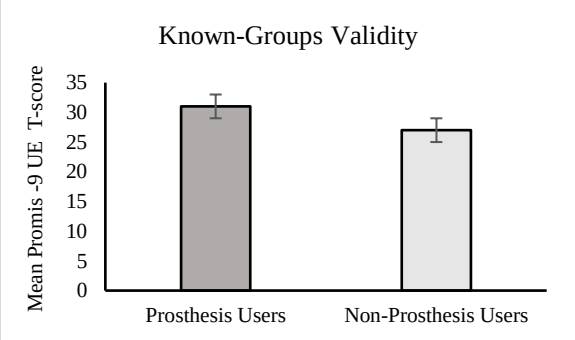

Figure 1: Prosthesis users had significantly higher physical functioning scores when compared to non-users.

Reliability

The average IRT reliability estimate for T-scores values found for the middle (28-70) of the scale was 0.9 indicating adequate reliability. Figure 2 showed that as the information increased the reliability simultaneously increased. Similarly, the traditional Cronbach's alpha analysis revealed adequate reliability value of 0.93 for the entire scale.

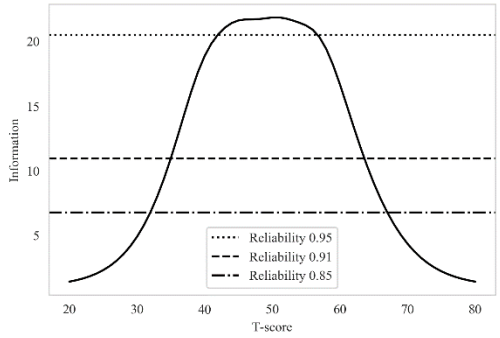

Figure 2: Information plotted across range of T-scores. The T-score range of 29-70 has the greatest level of precision. The reliability reference line of 0.95 correspond to an information magnitude of 10.

DISCUSSION

The purpose of this study was to examine the psychometric performance of the PROMIS-9 UE among individuals with UE amputation and this was achieved. Study results demonstrated no significant violation of validity, reliability and differential item functioning.

Hung et al. concluded that the PROMIS v1.2 UE item bank for physical function was structurally valid for individuals among upper limb complaint and further noted that more challenging questions are needed to capture higher functioning individuals. Similarly, our graded response model reported strong performance among UE amputees and also reaffirm the need for the addition of more difficult questions to the existing item bank. For example, if more challenging questions are added to the bank, then the two of the four items in the PROMIS-9 UE with similar range of item difficulty could be replaced with more challenging ones. Yet, the need for refinement does not preclude the administration of this instrument at baseline assessment and perhaps follow up visits for patients' with low to moderate levels of functionality.

This study is not without limitation. Future study should consider the performance of the PROMIS-9 UE with longitudinal data. This will demonstrate how well the instrument can track changes in patients' functional status. Lastly, future study should consider the impact of device type on the increase or decrease of patients' physical functioning T-Scores.

In conclusion, although challenging questions are needed to provide coverage for individuals with high actively levels, the PROMIS-9 UE is psychometrically sound and can be administer to patients with low to moderate physical function activity level.

ACKNOWLEDGEMENTS

Thanks to Mandi for assistance with data consolidation

REFERENCES

[1] E. Makhni, M. Meadows, J. Hamamoto, J. Higgins, A. A. Romeo, and N. N. Verma, "Patient Reported Outcomes Measurement Information System (PROMIS) in the upper extremity: the future of outcomes reporting?," *J. Shoulder Elb. Surg.*, vol. 26, no. 2, pp. 352–357, 2017.

[2] H. Burger, F. Franchignoni, A. Heinemann, S. Kotnik, and A. Giordano, "Validation of the orthotics and prosthetics user survey upper extremity functional status module in people with unilateral upper limb amputation," *J. Rehabil. Med.*, vol. 40, no. 5, pp. 393–399, 2008.

[3] F. Fayad, M. Lefevre-colau, V. Gautheron, and Y. Mace, "Reliability , validity and responsiveness of the French version of the questionnaire Quick Disability of the Arm , Shoulder and Hand in shoulder disorders," vol. 14, pp. 206–212, 2009.

[4] A. Kaat *et al.*, "The expansion and validation of a new upper extremity item bank for the Patient-Reported Outcomes Measurement Information System® (PROMIS)," *J. Patient-Reported Outcomes*, vol. 3, no. 1, 2019.

[5] M. Hung, M. Voss, J. Bounsanga, A. Crum, and A. Tyser, "Examination of the PROMIS upper extremity item bank," *J. Hand Ther.*, vol. 30, no. 4, pp. 485–490, Oct. 2017.

[6] D. Cella *et al.*, "Initial Adult Health Item Banks and First Wave Testing of the Patient Reported Outcomes Measurement Information System (PROMIS) Network," *J Clin Epidemiol*, vol. 63, no. 11, pp. 1179–1194, 2011.

[7] T. Nguyen, H. Han, M. Kim, and K.Chan, "An introduction to item response theory for patient-reported outcome measurement," *Patient*, vol. 7, no. 1. Adis International Ltd, pp. 23–35, 2014.