The Relationship Between Patient Reported Outcomes Measurement Information System and Timed Up and Go Test in Patients Awaiting Total Knee Arthroplasty

Kaitlyn Elaine Sly, SPT, LAT-ATC

University of North Carolina-Chapel Hill

Division of Physical Therapy

Osteoarthritis (OA) is the leading cause of knee pain for adults over 50 years old and may lead to functional limitations, decreased mobility, and reduced quality of life.[1] To treat the symptoms and functional deficits imposed by OA, approximately 700,000 adults annually elect to undergo a total knee arthroplasty (TKA).[2] For this patient population, it is critical for clinicians to utilize appropriate measures to objectively report patient status, establish patient prognosis, and recognize those at risk for poor outcomes.

Patient reported outcome measures (PROMs) are commonly utilized in clinical practice to collect subjective patient information. However, PROMs measure patient perception of function and have been described as less appropriate to assess function after surgery.[3] The Patient Reported Outcomes Measurement Information System (PROMIS) was initiated in 2004 by the US National Institutes of Health.[4,5] PROMIS utilizes psychometric techniques to collect information with relative brevity from subjective responses provided by patients.[4-7] The item response theory is used to recognize the underlying constructs being measured by each question and selects subsequent questions to be used to measure a participant on a construct continuum.[5,8] Additionally, by using computerized adaptive testing (CAT), a computer program is able to interpret an answer to a question and administer the following question at a higher or lower level to more accurately measure a construct.[8] Through these methods, the PROMIS CAT is able to estimate health-related domains, such as pain intensity, fatigue, or physical function, in approximately 4 to 6 questions.[8] CAT has the advantage of tailoring the measure to an individual, which reduces the burden of test administration and makes a comprehensive assessment more clinically feasible.[9]

The PROMIS physical function domain is pertinent for use in a patient population with knee OA because it measures an individual's ability to complete activities ranging from activities of daily living to more vigorous activities, which require mobility, strength, or endurance.[4] Items in this domain address the degree to which health limits physical abilities, such as climbing stairs; patient responses may range from "not at all," indicating no physical limitation, to "cannot do," indicating complete limitation.[10] Other items address the level of difficulty experienced while carrying out activities, such as vacuuming; responses range from "without any difficulty" to "unable to do."[10] Knee OA is significantly associated with functional limitations,[11] and people with severe knee pain report difficulties going up and down stairs, standing, walking, and completing heavy domestic duties.[12] Therefore, it is clinically relevant to utilize a tool to assess the physical function of patients considering TKA surgery.

The PROMIS CAT has the potential to quickly assess a patient's physical function before and after a TKA, but there is little research available comparing it to other functional measures. The Timed Up and Go (TUG) test is a simple functional outcome measure commonly used in clinical practice to assess mobility and fall risk in adults.[13] Research indicates that knee OA is significantly associated with slower walking times,[11] demonstrating the utility of the TUG test for individuals considering a TKA. Furthermore, literature describes the ability of the TUG test to predict post-surgical functional status and hospital length of stay following a joint replacement.[3] However, the TUG test might be prohibitive due to lack of space, reluctance of the patient to perform the test, and inability of the patient to follow multi-step commands. Currently, there is a lack of available evidence comparing the PROMIS CAT with the TUG test. Therefore,

the purpose of this study was to determine the strength of the relationship between the PROMIS CAT physical function domain and the TUG test in patients with severe knee OA who are candidates for a TKA.

Methods

Participants.

Participants were recruited from a university-affiliated orthopedic surgery clinic between August 2015 and March 2016. Participants were required to have a diagnosis of severe knee OA and be offered the option to undergo a TKA by an orthopedic surgeon to be included in the study. Participants were excluded from the study if they had the following characteristics: under the age of 18 years old; unable to speak English; history of previous major knee surgeries, traumatic, and/or rheumatic arthritis; and/or concomitant physical or psychological conditions which would prevent participation in physical therapy. The study was approved by the Institutional Review Board (IRB), and all subjects provided informed written consent for participation.

Study Design.

This study was a secondary analysis of an ongoing randomized controlled trial examining the effect of pre-operative physical therapy on patient outcomes following a TKA. A single time point from among the 4 time points collected for the original study was used in this secondary analysis. The enrollment time point was chosen for this analysis because participants had not yet been randomized to an intervention, which limits potential confounding factors. Enrollment data was collected approximately 12 weeks before anticipated surgery. The PROMIS CAT physical function domain, TUG test, and numeric pain rating scale (NPRS) were collected.

Measures.

PROMIS: The PROMIS physical function domain was accessed through http://www.assessmentcenter.net and administered through CAT on a handheld tablet device. Survey length typically consisted of 4 questions. Patients were blinded to PROMIS results. Raw PROMIS scores were converted into a T-score with a mean of 50 and a standard deviation (SD) of 10.[14] Therefore, scores lower than 50 indicated poorer physical function compared to the national average.[14] Broderick et al [6] has validated the PROMIS physical function domain for people with OA compared to the general population. Additionally, adequate test-retest reliability has been described.[6]

TUG Test: The TUG test is a measure of the time for a participant to stand from a chair, walk ten feet, turn around, walk back to the chair, and sit down.[3] Research indicates that adults between the ages of 60 to 69 years old complete the TUG test in a mean time of 8 seconds.[15] The TUG test has been validated for use in a patient population of community dwelling older adults and has demonstrated reliability in patients awaiting a TKA.[2,15-17] Moreover, the TUG test is responsive for detection of deterioration and improvement in the early post-operative period.[17]

Pain Intensity: Pain was recorded using the NPRS, typically before the TUG test and PROMIS CAT were administered. For this self-report measure, the subjects were asked to indicate the intensity of their current pain by using an 11-point numeric scale, ranging from 0 (no pain) to 10 (worst pain).[18] The general population has been reported to have a pain average ranging from 1 to 3 on the NPRS, while people with OA typically have a higher average score ranging from 5 to 6 on the NPRS.[6] The NPRS has been described as valid for a patient population with chronic

pain conditions and has demonstrated high test-retest reliability in patients with rheumatoid arthritis.[19]

Statistical Analysis.

Participant characteristics were tabulated using REDCap (REDCap Software, Version 6.5.16). All other statistical analyses were performed using JMP (SAS Institute Inc., Version 12.0.1). The analyses reported were limited to enrollment data obtained from participants who met eligibility criteria and were enrolled in the study. Missing variables were addressed using the restricted maximum likelihood (REML) method. Pearson's r was used to measure the linear correlation between the variables. Pearson's r values were used to determine the convergent validity of the TUG test, PROMIS CAT, and NPRS. A p-value ≤ 0.05 was used to identify correlation probability.

Results

The analysis included data from 59 participants (female = 63.3%, mean age = 62.57 years, mean BMI = 32.75 kg/m^2) (Table 1). The data set had missing values: a single TUG test was not recorded secondary to subject refusal, a single NPRS score was not recorded, and 4 PROMIS CAT physical function scores were not recorded secondary to a faulty internet connection and/or difficulties with the handheld tablet device.

Simple statistics for the PROMIS CAT physical function scores, TUG test, and NPRS were reported in Table 2. PROMIS CAT physical function scores had a significant moderate, negative correlation with the TUG test (r = -0.47, 95% CI = -0.66 to -0.23) (Table 3). This indicates that better ratings of physical function were associated with faster times on the TUG test. The

PROMIS domain accounted for 22.9% of the variance (R^2) in the TUG test. NPRS had no significant correlation to PROMIS CAT physical function scores (r = -0.24, 95% CI = -0.48 to 0.03) or to the TUG test (r = 0.24, 95% CI = -0.02 to 0.47) (Table 3).

Discussion

The TUG test is a commonly utilized functional outcome measure that assesses mobility and fall risk in adults.[13] Bade et al[20] examined the predictive ability of the TUG test in adults waiting to undergo a TKA, reporting that patients completing the TUG test pre-operatively in greater than 10.1 seconds and who were older than 72 years had the poorest results on the TUG test 6 months post-TKA. This study sample included 7 subjects who completed the TUG test in greater than 10.1 seconds and who were older than 72 years, indicating they may be at risk for poorer outcomes. Their mean PROMIS CAT and NPRS scores were 36.86 ± 8.29 and 6.71 ± 2.43, respectively. Furthermore, Poitras et al[3] described a post-operative TUG test time greater than 30.9 seconds as an indicator of slower functional recovery following a total joint replacement. Though the TUG test has utility in a patient population with severe knee OA, inadequate space, decreased patient motivation, and inability to follow multi-step commands may prevent the test from being performed.

PROMIS CAT is a unique system, which can quickly assess a patient's subjective appraisal of physical function. However, PROMIS CAT only showed a moderate, negative correlation to the TUG test in this study, indicating its limited convergent validity with this physical function test. These results are similar to those published by Driban et al[10] who determined PROMIS physical function domain scores correlated well with SF-36 physical function scores (r = 0.79) but did not

correlate as strongly with functional measures, such as gait speed (r = -0.43) and 6-minute walk times (r = 0.46). Therefore, important information about patient-reported physical function may be gained using PROMIS CAT; however, it does not seem to be a surrogate for physical performance measures.

Interestingly, results of this study also revealed no significant correlation between a self-report measure for pain, the NPRS, and measures of physical functioning, including the TUG test and the PROMIS CAT physical function domain. Terwee et al[21] published similar results when assessing a physical function test compared to the self-report pain subscales of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the SF-36 in a patient population awaiting a TKA. Convergent validity between the physical function test and subjective pain subscales was limited and reported as r = 0.20 for the WOMAC and r = 0.26 for the SF-36.[21] Further literature suggests that the NPRS is inadequate for patients with knee OA because it is unable to capture the complex nature of symptom fluctuations.[19]

Continued research should be performed to examine the utility of different PROMIS domains and CAT for a patient population with severe knee OA. Additionally, this study only evaluated measures at a single time point; further research should be performed to describe the predictive validity of outcome measures, such as the PROMIS, over time. By examining the predictive qualities of these measures, clinicians may better identify patients at risk for poor functional outcomes before undergoing a TKA. As a result, additional rehabilitation and appropriate discharge planning may be performed to maximize patient outcomes.

Study Limitations.

There are limitations to note in this study. First, the order of outcome measures administered typically followed a standardized pattern across participants; therefore, fatigue and order bias may have influenced patient responses on the NPRS and PROMIS CAT or physical performance on the TUG test. Second, analysis included any data collected from participants at enrollment. Therefore, data was missing if a participant was unable to complete an outcome measure. In total, a single TUG test, a single NPRS score, and 4 PROMIS values were missing from the data set. However, missing data was accounted for using the REML method, which uses available data to calculate an acceptable estimate.

Conclusion

In conclusion, the TUG test had a significant moderate, negative correlation with the PROMIS CAT physical function domain in participants with severe knee OA. Additionally, the PROMIS CAT accounted for a limited amount of variance in the data. The NPRS had no significant correlation to the TUG test and the PROMIS CAT physical function domain. Therefore, clinicians should consider utilizing a variety of self-report and functional outcome measures to adequately assess patients with severe knee OA who are candidates for undergoing a TKA.

Acknowledgements

I recognize the University of North Carolina Orthopedic Department for their contribution to data collection, the Department of Allied Health's biostatistician for advisement in data analysis, and the gracious contribution of advisors at the University of North Carolina throughout the research process. Use of REDCap was made possible through grant support from the Clinical and Translational Science Award program of the Division of Research Resources, National Institutes of Health.

References

1. Nguyen US, Zhang Y, Zhu Y, Niu J, Zhang B, Felson DT. Increasing prevalence of knee pain and symptomatic knee osteoarthritis: Survey and cohort data. *Ann Intern Med*. 2011;155(11):725-732.

2. Bade MJ, Kittelson JM, Kohrt WM, Stevens-Lapsley JE. Predicting functional performance and range of motion outcomes after total knee arthroplasty. *Am J Phys Med Rehabil*. 2014;93(7):579-585.

3. Poitras S, Wood KS, Savard J, Dervin GF, Beaule PE. Predicting early clinical function after hip or knee arthroplasty. *Bone Joint Res*. 2015;4(9):145-151.

4. The Patient Reported Outcomes Measurement Information System (PROMIS): A Walk Through the First Four Years. http://www.nihpromis.org/Documents/PROMIS_The_First_Four_Years.pdf. Updated 2009. Accessed April 9, 2016.

5. Rose M, Bjorner JB, Gandek B, Bruce B, Fries JF, Ware JE,Jr. The PROMIS physical function item bank was calibrated to a standardized metric and shown to improve measurement efficiency. *J Clin Epidemiol*. 2014;67(5):516-526.

6. 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(10):1625-1633.

7. Fries JF, Cella D, Rose M, Krishnan E, Bruce B. Progress in assessing physical function in arthritis: PROMIS short forms and computerized adaptive testing. *J Rheumatol*. 2009;36(9):2061-2066.

8. Hanmer J, Feeny D, Fischhoff B, et al. The PROMIS of QALYs. *Health Qual Life Outcomes*. 2015;13:122.

9. Hung M, Clegg DO, Greene T, Saltzman CL. Evaluation of the PROMIS physical function item bank in orthopaedic patients. *J Orthop Res*. 2011;29(6):947-953.

10. 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.

11. Zambon SS. Osteoarthritis, comorbidity and pain: Their role in determining functional limitations in older populations (European project on osteoarthritis). *Arthritis Care Res*. 2015.

12. Jinks C, Ong BN, Richardson J. A mixed methods study to investigate needs assessment for knee pain and disability: Population and individual perspectives. *BMC Musculoskelet Disord*. 2007;8:59.

13. Shumway-Cook A, Brauer S, Woollacott M. Predicting the probability for falls in community-dwelling older adults using the timed up & go test. *Phys Ther*. 2000;80(9):896-903.

14. Physical function. https://www.assessmentcenter.net/documents/PROMIS%20Physical%20Function%20Scoring%20Manual.pdf. Updated 2015. Accessed April 13, 2016.

15. Steffen TM, Hacker TA, Mollinger L. Age- and gender-related test performance in community-dwelling elderly people: Six-minute walk test, berg balance scale, timed up & go test, and gait speeds. *Phys Ther*. 2002;82(2):128-137.

16. Podsiadlo D, Richardson S. The timed "up & go": A test of basic functional mobility for frail elderly persons. *J Am Geriatr Soc*. 1991;39(2):142-148.

17. Kennedy DM, Stratford PW, Wessel J, Gollish JD, Penney D. Assessing stability and change of four performance measures: A longitudinal study evaluating outcome following total hip and knee arthroplasty. *BMC Musculoskelet Disord*. 2005;6:3.

18. Young IA, Cleland JA, Michener LA, Brown C. Reliability, construct validity, and responsiveness of the neck disability index, patient-specific functional scale, and numeric pain rating scale in patients with cervical radiculopathy. *Am J Phys Med Rehabil*. 2010;89(10):831-839.

19. Hawker GA, Mian S, Kendzerska T, French M. Measures of adult pain: Visual analog scale for pain (VAS pain), numeric rating scale for pain (NRS pain), McGill pain questionnaire (MPQ), short-form McGill pain questionnaire (SF-MPQ), chronic pain grade scale (CPGS), short

226 form-36 bodily pain scale (SF-36 BPS), and measure of intermittent and constant osteoarthritis
227 pain (ICOAP). *Arthritis Care Res*. 2011;63(S11):S240-S252.

228 20. Bade MJ, Wolfe P, Zeni JA, Stevens-Lapsley JE, Snyder-Mackler L. Predicting poor
229 physical performance after total knee arthroplasty. *J Orthop Res*. 2012;30(11):1805-1810.

230 21. Terwee CB, van der Slikke RM, van Lummel RC, Benink RJ, Meijers WG, de Vet HC. Self-
231 reported physical functioning was more influenced by pain than performance-based physical
232 functioning in knee-osteoarthritis patients. *J Clin Epidemiol*. 2006;59(7):724-731.

Table 1: Participant Characteristics

n	59
Male	36.7%
Female	63.3%
Age* (Mean ± SD[+]) (Range)	62.57 ± 8.51 (38.8 – 78.4)
BMI[±] (Mean ± SD[+]) (Range)	32.75 ± 5.46 (22.7 – 47.3)

*Age reported in years; [+]SD = Standard Deviation; [±]BMI = Body Mass Index reported in units of kg/m^2

238 **Table 2: Univariate Simple Statistics**

	n	**Mean**	**SD**[§]	**Range**
TUG* (s)	58	16.66	7.66	7.50 - 42.22
PROMIS[+]	55	38.69	6.42	27.00 - 54.00
NPRS[±]	58	6.84	2.50	0.00 - 10.00

239

240 * TUG = Timed Up and Go; [+] PROMIS = Patient Reported Outcomes Measurement Information

241 System; [±] NPRS = Numeric Pain Rating Scale; [§] SD = Standard Deviation

Table 3: Correlation of TUG, PROMIS, and NPRS

	Correlation (*r*)	**CI[§]**	***p*-Value**
TUG*, PROMIS[+]	-0.47	-0.66 to -0.23	0.0003[‖]
TUG, NPRS[±]	0.24	-0.02 to 0.47	0.0686
PROMIS, NPRS	-0.24	-0.48 to 0.03	0.0750

* TUG = Timed Up and Go; [+] PROMIS = Patient Reported Outcomes Measurement Information System; [±] NPRS = Numeric Pain Rating Scale; [§] CI = 95% Confidence Interval; [‖] *p*-value indicates a significant correlation