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PROMIS Physical Function and Pain Interference Scores Correlate with the Lower Extremity Toronto Extremity Salvage Score

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Investigation performed at Washington University School of Medicine in St. Louis, St. Louis, Missouri

Background: The Toronto Extremity Salvage Score (TESS) and the National Institutes of Health Patient-Reported Outcomes Measurement Information System (PROMIS) are both utilized to measure patient-reported outcomes in adults with musculoskeletal oncologic conditions. However, the relationship between them has not been studied. We sought to describe a link between Lower Extremity (LE) TESS and PROMIS Physical Function (PF) scores, as well as between LE TESS and Pain Interference (PI) scores, to develop a method for converting scores between TESS and PROMIS and to examine whether TESS and PROMIS captured differences in pain and function between clinically relevant subgroups in our population.

Methods: Our study population consisted of 125 adult patients who underwent surgical treatment of a lower-extremity musculoskeletal tumor at a single sarcoma center between December 2015 and October 2018. The LE TESS questionnaire was administered to patients via paper and the PROMIS PF and PI were administered via iPad at a preoperative appointment. The relationship between LE TESS and PROMIS measures was analyzed with use of generalized linear modeling. Subgroup analyses were performed with a 2-tailed t test or 1-way analysis of variance.

Results: PROMIS PF had a very strong positive correlation with LE TESS (r = 0.83) and was related through the following equation: *PROMIS PF* = $0.00294 \times (LE TESS)^2 + 22.6$. PROMIS PI had a strong negative correlation with LE TESS (r = -0.77) and was related through the following equation: *PROMIS PI* = $-0.00259 \times (LE TESS)^2 + 73.8$. PROMIS PF and PI performed similarly to LE TESS across multiple patient subgroups and captured the expected differences between subgroups.

Conclusions: LE TESS and PROMIS PF appeared to measure similar information in patients with an orthopaedic oncologic condition. Moreover, PROMIS PI scores were strongly correlated with functional disability as measured with the LE TESS. Understanding the relationship between TESS and PROMIS will allow the comparison and combination of data for both clinical and research purposes.

Level of Evidence: Prognostic Level III. See Instructions for Authors for a complete description of levels of evidence.

If istorically, patient outcomes in medicine have been assessed by physicians. The field of orthopaedic oncology, for example, has traditionally relied on the Musculoskeletal Tumor Society (MSTS) score, which was introduced in 1987 and updated in 1993. However, the determination of disability made by a physician can differ from that made by the patient¹, and the importance of patient-reported outcomes (PROs) has been increasingly recognized across medical fields²⁻⁷. Accordingly, the Toronto Extremity Salvage Score (TESS) was developed as a patient-reported measure of func-

tional disability in adult patients with surgically treated musculoskeletal tumors in the upper or lower limb. Currently, the TESS and MSTS (1993) questionnaires are the most commonly utilized measures of functional outcomes in adult patients with lower-extremity tumors⁸.

The Patient-Reported Outcomes Measurement Information System (PROMIS) was developed by the National Institutes of Health to measure various patient-reported measures in any adult population. PROMIS can capture multiple aspects of wellbeing through >100 item banks that measure patient perceptions

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in musculoskeletal oncology.

Materials and Methods

of their health in 102 different domains, such as physical func-

tion, pain, social satisfaction, and emotional distress. In addition,

research has shown that PROMIS decreases floor and ceiling

effects as well as responder burden through its use of computer

adaptive tests and item response theory9-11. A previous study

comparing the time taken to complete PROMIS Physical

Function (PF) versus Lower Extremity (LE) TESS surveys among

patients with lower-extremity bone metastases demonstrated

that 73% of participants completed the PROMIS PF in <1

minute, whereas the mean time to complete the LE TESS was >4

minutes¹². Finally, PROMIS reduces administrative error be-

cause no manual calculation or data entry is required and scores

are automatically entered into the electronic medical record once

the surveys are completed, eliminating the possibility of forget-

ting to fill out the back side of a double-sided paper or misin-

terpretation of inaccurate marks. These advantages provided by

PROMIS over other PRO measures have led to its increased use

across medical fields, including orthopaedics4,5,13,14 and oncol-

ogy^{2,3,6,15-17}. The PROMIS PF and Pain Interference (PI) domains

have been validated in various orthopaedic^{4,5,13,14} and oncologic

populations^{2,3,6,15-17}; however, they have not been as well studied

universally utilized in orthopaedic oncology, preventing the

combination of data across institutions as well as the comparison

of studies within the existing literature. These research limita-

tions are especially unfortunate because sarcomas are both rare

and diverse, which makes it challenging to collect a meaningful number of cases for study. In the absence of a common

measure, understanding the relationship between existing mea-

sures would facilitate the accumulation of data and the develop-

ment of evidence-based care. Therefore, our goals were to calculate

the correlation of LE TESS with each PROMIS domain (PF or PI), to define a mathematical relationship between LE TESS and

PROMIS PF and between LE TESS and PROMIS PI in order to enable comparison of those measures, and to determine whether

LE TESS, PROMIS PF, and PROMIS PI capture differences in pain

pproval for this study was obtained from the institutional

 Λ review board at the Washington University School of

Medicine in St. Louis, and informed consent was obtained

from all patients. The study population consisted of 125 con-

secutive adult patients with a lower-extremity bone or soft-

and function between various clinically relevant subgroups.

None of the aforementioned outcome measures have been

tissue tumor who received preoperative outpatient evaluation and surgical treatment between December 2015 and October 2018 at a single, university-based, tertiary care institution.

At their preoperative appointment, patients completed the LE TESS questionnaire via paper and the PROMIS PF (PROMIS Bank v1.2 and v2.0 - Physical Function) and PROMIS PI (PROMIS Item Bank v1.1 - Pain Interference) via tablet computer (mini iPad; Apple). The median number of LE TESS questions answered was 32 (interquartile range [IQR], 1 to 32), the median number of PROMIS PF questions answered was 4 (IQR, 4 to 12), and the median number of PROMIS PI questions answered was 4 (IQR, 4 to 12). LE TESS surveys were manually entered into a secure database and then scored via a Microsoft Excel algorithm. PROMIS surveys were collected over a secure wireless network, scored, and immediately stored in the electronic medical record. The median length of time between the preoperative appointment and surgery was 13 days (IQR, 6 to 22 days) (Table I).

The TESS ranges from 0 to 100 and is calculated by dividing the sum of patient responses to questions by the maximum possible score based on the number of questions answered. Higher scores indicate less disability, whereas lower scores indicate more disability. PROMIS scores are set on a normal distribution centered at 50 with a standard deviation of 10. For PROMIS PF, higher scores indicate more physical function, whereas lower scores indicate less physical function. For PROMIS PI, higher scores indicate more pain interference, whereas lower scores indicate less pain interference.

Statistical Analysis

The statistical analysis was performed with use of SAS version 9.4 (SAS Institute) and Microsoft Excel 2016. A general linear model analysis package was utilized to analyze the relationship between LE TESS and PROMIS PF as well as between LE TESS and PROMIS PI. Curve fitting was performed, and correlation coefficients were derived from the r² of the model. Correlation coefficients were interpreted as proposed by Evans (0.00 to 0.19, very weak; 0.20 to 0.39, weak; 0.40 to 0.59, moderate; 0.60 to 0.79, strong; 0.80 to 1.00, very strong)¹⁸. Bivariate analyses were conducted to detect differences in scores for PROMIS PF, PROMIS PI, and LE TESS between relevant demographic and clinical subgroups. The effects of patient age and the number of days between the preoperative appointment and surgery were analyzed with use of simple linear regression and the Pearson correlation coefficient. The effects of patient gender and tumor characteristics (i.e., soft tissue compared with bone, primary compared with

TABLE I Patient Age and Time from Preoperative Appointment to Surgery								
		Correlation with LE TESS		Correlation with PROMIS PF		Correlation with PROMIS PI		
Patient Characteristics	Median (IQR)	Pearson Correlation Coefficient (r)	P Value	Pearson Correlation Coefficient (r)	P Value	Pearson Correlation Coefficient (r)	P Value	
Patient age in years Days before surgery	53 (40-68) 13 (6-22)	-0.13 0.10	0.14 0.26	-0.20 0.23	0.03 0.01	-0.05 -0.15	0.56 0.09	

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Characteristics	No. (%)	Mean LE TESS (Range)	Mean PROMIS PF Score (Range)	Mean PROMIS PI Score (Range)
Gender†				
Female	62 (50%)	75.4 (6.7-100)	41.4 (39-84)	57.7 (20-70)
Male	63 (50%)	74.7 (0-100)	40.9 (39-78)	57.5 (19-73)
Difference in means		0.7	0.5	0.2
2-tailed t test		P = 0.87	P = 0.79	P = 0.91
Location [‡]				
Pelvis	12 (10%)	67.0 (12.5-100)	36.4 (19-55)	62.1 (39-74)
Thigh	54 (43%)	70.9 (6.7-100)	40.9 (20-66)	55.9 (39-74)
Knee	24 (19%)	80.0 (10-100)	42.1 (20-60)	57.8 (39-78)
Calf	25 (20%)	80.0 (0-100)	42 (20-73)	57.6 (39-84)
Foot	10 (8%)	82.6 (67.5-98.3)	44.2 (36-70)	60.6 (47-74)
1-way ANOVA		P = 0.29	P = 0.55	P = 0.40
Soft tissue vs. bone‡				
Soft tissue	88 (70%)	81.4 (0-100)	44.5 (19-73)	54.8 (39-74)
Bone	37 (30%)	60.1 (10-100)	33.2 (20-51)	64.2 (39-84)
Difference in means		21.3	11.3	-9.4
2-tailed t test		P < 0.001	P < 0.001	P < 0.001
Primary vs. metastatic‡				
Primary	111 (89%)	80.0 (0-100)	43.1 (19-73)	56.3 (39-84)
Metastatic	14 (11%)	35.6 (10-67.3)	25.6 (20-32)	67.7 (39-78)
Difference in means		44.4	17.5	-11.4
2-tailed t test		P < 0.001	P < 0.001	P < 0.001
Benign vs. malignant‡				
Benign	66 (53%)	82.3 (19.2-100)	44.7 (20-73.3)	56.0 (38.7-83.8)
Malignant	59 (47%)	67 (0-100)	37.2 (19.1-60.4)	59.0 (38.7-77.8)
Difference in means		15.3	7.5	-3.0
2-tailed t test		P = 0.001	P < 0.001	P = 0.12

*For each factor, the frequency in the study population; the mean LE TESS, PROMIS PF, and PROMIS PI scores; and the association between the characteristic and outcome measure scores are shown. Significant p values are shown in bold. †Values are given as the number and percentage of patients. †Values are given as the number and percentage of tumors.

metastatic, benign compared with malignant) were analyzed with use of 2-tailed Welch t testing. A subgroup analysis of tumor location was performed with use of 1-way analysis of variance (ANOVA). The level of significance was set at $\alpha = 0.05$.

Source of Funding

No external funding was received for this study.

Results

The median age of the 125 included patients was 53 years (IQR, 40 to 68 years), and there were similar proportions of men and women (Tables I and II). Of the tumors, 30% (37 of 125) were bone tumors, whereas 70% (88 of 125) were soft-tissue tumors. The majority of tumors (53% [66 of 125]) were benign, and the most common anatomic location of tumor occurrence was the thigh (43% [54 of 125 tumors]) (Table II). Based on the final histopathologic diagnosis, the most common subtypes of

bone tumor were metastatic carcinoma, chondrosarcoma, and osteosarcoma, whereas the most common subtypes of soft-tissue tumor were lipoma, undifferentiated pleomorphic sarcoma, synovial sarcoma, and simple cyst (Tables III and IV).

PROMIS PF had a very strong positive correlation with LE TESS (r = 0.83), demonstrating that better physical function (measured with PROMIS PF) was correlated with less disability (measured with LE TESS) (Fig. 1). PROMIS PI had a strong negative correlation with LE TESS (r = -0.77), showing that more pain (measured with PROMIS PI) was correlated with greater disability (measured with LE TESS) (Fig. 2).

The relationship between LE TESS and PROMIS PF and that between LE TESS and PROMIS PI were mathematically defined with the following equations, respectively:

PROMIS Physical Function=0.00294*(LE TESS)²+22.6 PROMIS Pain Interference=-0.00259*(LE TESS)²+73.8

TABLE III Histopathologic Diagnoses of Bone Tumors (N = 37)					
Bone Tumor Subtype	No. of Tumors (%)				
Metastatic carcinoma	14 (37.8)				
Chondrosarcoma	8 (21.6)				
Osteosarcoma	3 (8.1)				
Enchondroma	2 (5.4)				
Giant cell tumor	2 (5.4)				
Osteochondroma	2 (5.4)				
Aneurysmal bone cyst	2 (5.4)				
Solitary bone cyst	2 (5.4)				
Ewing sarcoma	1 (2.7)				
Multiple myeloma	1 (2.7)				

Patients with a bone tumor had lower scores for LE TESS (mean difference, 21; p < 0.001), lower PROMIS PF scores (mean difference, 11; p < 0.001), and higher PROMIS PI scores (mean difference, 9; p < 0.001) than those with a soft-tissue tumor (Table II). Patients with a metastatic tumor had lower scores for LE TESS (mean difference, 44; p < 0.001), lower PROMIS PF scores (mean difference, 18; p < 0.001), and higher PROMIS PI scores (mean difference, 11; p < 0.001) than those with a primary tumor (Table II). Patients with a malignant tumor had lower scores for LE TESS (mean difference, 11; p < 0.001) than those with a primary tumor (Table II). Patients with a malignant tumor had lower scores for LE TESS (mean difference, 8; p < 0.001) and lower PROMIS PF scores (mean difference, 8; p < 0.001) than those with a benign tumor; however, the difference in PROMIS PI scores between these 2 subgroups was not significant (mean difference, 3; p = 0.12) (Table II).

No strong correlations were found between TESS or PROMIS scores and patient gender, age, or associations between them and tumor location (Tables I and II).

Discussion

PROs have been increasingly utilized to better understand patient wellness and to better guide clinical management. Compared with previous PRO measures, PROMIS has advantages such as public availability for ease of access, utilization of computer adaptive tests and short forms to increase accuracy and to reduce responder burden, and standardization to allow for easier comparison and interpretation. The present study was built on previous work, which demonstrated that PROMIS PF and PI had very strong positive and strong negative correlations, respectively, with LE TESS in patients with musculoskeletal tumors⁹. We further explored these relationships by generating unique models to convert scores between LE TESS and PROMIS PF or PI and by performing subgroup analyses to detect differences in scores between patients with various demographic and tumor characteristics.

Correlation and Mathematical Relationship Between LE TESS and PROMIS PF or PI

PROMIS PF and PI had a very strong positive (r = 0.83) and strong negative (r = -0.77) correlation, respectively, with LE

TESS. Our findings replicate the strength and directionality of the correlation between LE TESS and each of these 2 PROMIS domains shown in prior literature⁹. To further define the relationship between these systems, we calculated a mathematical relationship between PROMIS PF and LE TESS and between PROMIS PI and LE TESS that investigators can use to convert scores between measures.

Our proposed equations have several potential applications. In the clinical setting, providers would be able to understand the outcomes reported by their patients in the context of both PROMIS and TESS literature, even when only 1 of the measures was administered. In the research setting, the development of conversion models such as these would optimize the value of new and existing literature by making studies that use TESS and those that use PROMIS mutually intelligible. In addition, bridging these outcome measures is a crucial step toward producing high-powered research in the field of orthopaedic oncology. Sarcoma is a rare and heterogeneous group of diseases, which increases the challenge of collecting sufficient data to develop evidence-based recommendations. The MSTS recognized this issue and has since aimed to increase collaborative and multi-institutional research projects through the establishment of the Musculoskeletal Oncology Research Initiative (MORI) and through the funding of multicenter trials such as Prophylactic Antibiotic Regimens in Tumor Surgery (PARITY) and Surveillance After Extremity Tumor Surgery (SAFETY).

TABLE IV Histopathologic Diagnoses of Soft-Tissue Tumors (N = 88)					
Soft-Tissue Tumor Subtype	No. of Tumors (%)				
Lipoma	17 (19.3)				
Undifferentiated pleomorphic sarcoma	11 (12.5)				
Synovial sarcoma	6 (6.8)				
Simple cyst	6 (6.8)				
Myxoma	5 (5.7)				
Myxofibrosarcoma	5 (5.7)				
Neurilemmoma	5 (5.7)				
Pigmented villonodular synovitis	5 (5.7)				
Liposarcoma	4 (4.5)				
Sarcoma, unspecified	4 (4.5)				
Ganglion cyst	4 (4.5)				
Chondromyxoid fibroma	3 (3.4)				
Hemangioma	3 (3.4)				
Giant cell tumor of the tendon sheath	2 (2.3)				
Popliteal cyst	2 (2.3)				
Synovial chondromatosis	2 (2.3)				
Angiosarcoma	1 (1.1)				
Fibrosarcoma	1 (1.1)				
Hemangiopericytoma	1 (1.1)				
Sweat gland carcinoma	1 (1.1)				

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LE TESS vs. PROMIS PF

PROMIS Physical Function Predicted from Lower Extremity TESS

Fig. 1

Scatterplot showing scores for LE TESS compared with PROMIS PF. The 2 measures had a very strong positive correlation (r = 0.83). A relationship between these 2 metrics was represented with the following equation: $PROMIS PF = 0.00294 \times (LE TESS)^2 + 22.6$.

The need for multi-institutional research collaboration has also been emphasized in the context of PROs, yet inconsistency in the measures that are utilized across institutions remains a limitation¹⁹. PROs of function among patients with lower-extremity soft-tissue sarcomas were investigated in a systematic review by Kask et al., who demonstrated that TESS was utilized in 43% of the studies and that the MSTS score was utilized in 32%⁸. A total of 8 other previously reported measures were utilized in the remaining 25% of studies⁸. The use of such a wide variety of PRO measures in musculoskeletal oncology has made comparing and interpreting data between systems difficult. Ultimately, combining TESS and PROMIS data could generate the statistical power necessary to perform more definitive clinical studies and meta-analyses.

Both TESS and PROMIS are highly relevant in the field of orthopaedic oncology. TESS is currently the most widespread PRO measure in patients with musculoskeletal tumors of the extremities, and it has been validated in multiple countries as well as in both adult and pediatric patients²⁰⁻²⁵. Switching to a new system such as PROMIS would, on some level, disrupt the continuity of patient care and research databases; additionally, the implementation of PROMIS collection specifically may be hindered by logistical and financial barriers related to its electronic method of administration. The strengths of PROMIS include improved efficiency, reduced floor and ceiling effects, application across subspecialties, and ease of data collection and analysis. It also offers more specific information by providing individual scores for each domain, whereas TESS provides a single score encompassing all aspects of disability associated with musculoskeletal tumors. The use of both TESS and PROMIS systems in orthopaedic oncology will likely continue into the foreseeable future, making the need for a conversion model between them even more critical.

Patient and Tumor Characteristics in LE TESS and PROMIS PF and PI

We observed several associations between PRO scores and relevant clinicopathological variables. The effect of such characteristics on scores for the TESS has been investigated in several studies; however, the effect on PROMIS is incompletely understood in the context of musculoskeletal oncology. Wright et al. reported that social deprivation had no impact on PROMIS PF, PI, Depression, or Anxiety scores among patients with orthopaedic oncologic conditions²⁶. In the present study,

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Fig. 2

Scatterplot showing scores for LE TESS compared with PROMIS PI. The 2 measures had a strong negative correlation (r = -0.77). A relationship between these 2 metrics was represented with the following equation: *PROMIS PI* = $-0.00259 \times (LE TESS)^2 + 73.8$.

we have added to the current understanding of the PROMIS by investigating the effects of additional patient characteristics (i.e., gender and age) and tumor characteristics (i.e., tissue type, location, primary compared with metastatic, and benign compared with malignant) on PROMIS PF and PI scores in patients with a musculoskeletal oncology condition.

We found that scores for LE TESS and PROMIS PF and PI were not impacted by gender or tumor location within the lower extremity. The effect of gender on the LE TESS has been variably reported in the literature, with 1 study demonstrating that female gender is associated with worse postoperative scores⁷ but other studies demonstrating that gender differences do not exist²⁷⁻²⁹. However, the effect of tumor location within the lower extremity has not been previously reported. In the present study, PROMIS PF and PROMIS PI did capture other differences, such as those related to age and tumor type, that would be expected on the basis of existing literature. Older age and bone tumors (compared with soft-tissue tumors) have been associated with lower scores for the TESS7,28. In our population, we observed the same relationships for PROMIS PF, but the association between older age and greater disability did not reach significance for LE TESS, suggesting that PROMIS PF may be more sensitive for this measurement. PROMIS PI scores were higher in patients with a bone tumor, which was expected given the multiple factors that contribute to tumor-induced bone pain³⁰. Consistent with a study by Dalton et al., we found that scores for PROMIS PF and LE TESS were worse in patients with a malignant tumor, whereas PROMIS PI scores did not differ between patients with a benign tumor and those with a malignant tumor³¹. Finally, patients with metastatic cancer reported lower physical function on both LE TESS and PROMIS PF, as well as higher levels of pain on PROMIS PI, than patients with nonmetastatic cancer. These findings confirm that PROMIS is able to capture differences between clinically relevant subgroups.

Limitations

Our study had several limitations. Our data only included preoperative scores obtained at a clinical visit with a variable length of time until surgery. Our purpose was to compare matched scores for LE TESS and PROMIS that were collected simultaneously, making consistent timing between patients less relevant; however, it is possible that our findings would have been different if we had included postoperative scores. Previous

studies have identified similar demographic and oncologic factors that influence postoperative scores for TESS and PROMIS PF in patients with lower-extremity musculoskeletal tumors. Female gender, older age, higher body mass index, history of smoking, and having a bone (compared with soft-tissue) lesion were associated with worse postoperative scores in LE TESS in patients who underwent limb-salvage surgery for bone and soft-tissue sarcoma⁷. Similarly, worse early postoperative PROMIS PF scores were seen in patients with older age and female gender, and in those with malignant tumors³¹. Although these parallels suggest that scores for LE TESS and PROMIS after surgery are correlated, high-powered studies with longitudinal data are needed to determine whether the conversion equations that we have proposed remain accurate in the postoperative setting.

Lastly, to our knowledge, there is no established threshold for clinically relevant change in the PROMIS scores of patients with an orthopaedic oncologic condition. The minimal clinically important difference (MCID), or the smallest difference in scores that has implications for patient care³², has previously been calculated for LE TESS³³ as well as for PROMIS in other medical fields^{13,17,34}. Calculating the PROMIS MCID in our patient population was beyond the scope of our study, but further investigation could allow greater understanding of the relative sensitivities of the 2 different PROMIS measures.

Conclusions

PROMIS PF and PI scores were strongly correlated with scores for LE TESS, suggesting that they measure similar information in patients with an orthopaedic oncologic condition. Score conversion between LE TESS and PROMIS PF can be estimated with the equation

PROMIS Physical Function=0.00294*(LE TESS)² +22.6 (r=0.83) whereas conversion between LE TESS and PROMIS PI can be estimated with the equation

PROMIS Pain Interference=-0.00259*(LE TESS)² +73.8 (r=-0.77)

Moreover, the 3 measures consistently captured clinically relevant differences between subgroups, such as differences in patient pain and physical function depending on whether the tumor involved bone compared with soft tissue, primary compared with metastatic, and benign compared with malignant. Understanding the relationship between TESS and PROMIS will allow comparison and combination of data for both clinical and research purposes. Future investigations should be designed to confirm whether these relationships persist in the postoperative setting as well as in the upper extremity.

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