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Challenges and opportunities in trauma research: study designs and patient-reported outcome measures

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CHAPTER 12

Validation of PROMIS Physical Function for evaluating
outcome following acute Achilles tendon rupture

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Abstract

Background

There is increased demand for valid, reliable, and responsive patient-reported outcome measures (PROMs) to evaluate patients with an Achilles tendon rupture, but not all PROMs currently in use are reliable and responsive for this condition. The primary aim of this study was to evaluate the measurement properties of the more recent Patient Reported Outcomes Measurement Information System Physical Function (PROMIS PF) compared to different PROMs used in patients with an acute Achilles tendon rupture.

Methods

A retrospective cohort study with follow-up by questionnaire was performed using data from two academic centers. All adult patients with an acute Achilles tendon rupture between June 2016 and June 2018 with a minimum of 12 months follow-up were eligible for inclusion. Functional outcome was assessed using the Patient-Reported Outcomes Measurement Information System Physical Function (PROMIS PF) Computerized Adaptive Test (CAT), Foot and Ankle Ability Measure (FAAM) Activities of Daily Living (ADL), FAAM Sports, and Achilles Tendon Total Rupture Score (ATRS). Pearson's correlation (r) was used to assess the correlations between outcome measures. Absolute and relative floor and ceiling effects were calculated.

Results

In total, 103 patients were included. The mean age was 44.7 years (range 19-77) and 76 patients (74%) were male. A total of 82 patients (80%) underwent operative repair while the remainder, 21 patients (20%) underwent nonoperative management. The mean time between treatment to collection of PROMs was 25.3 months (range 15-36). The mean PROMIS PF was 55.4 (SD 9.2), FAAM ADL 92.9 (SD 12.2), FAAM Sports 77.7 (SD 22.9), and ATRS 83 (SD 19.4). The ATRS was correlated with FAAM ADL (r 0.80; 95%CI 0.72; 0.86; $p < 0.001$) and FAAM Sports (r 0.86; 95%CI 0.80; 0.90; $p < 0.001$). The PROMIS PF was correlated with the FAAM ADL (r 0.66; 95%CI 0.53; 0.75; $p < 0.001$), FAAM Sports (r 0.65; 95%CI 0.53; 0.75; $p < 0.001$), and ATRS (r 0.69; 95%CI 0.58; 0.78; $p < 0.001$). The PROMIS PF did not show absolute floor or ceiling effects (0%). The FAAM ADL (35.9%), FAAM Sports (15.8%), and ATRS (20.4%) had substantial absolute ceiling effects.

Conclusion

The PROMIS PF, FAAM ADL, and FAAM Sports all showed a moderate to high mutual correlation with the ATRS. Notably, however, of all these measures only PROMIS PF avoided substantial floor and ceiling effects. The results of this study suggest the PROMIS PF CAT can be considered a valid, reliable and perhaps the most responsive tool to evaluate patient outcomes after treatment of an Achilles tendon rupture.

Introduction

The incidence of Achilles tendon ruptures is rising not only among young patients, but also among an increasingly aging, but active, population.¹ The role of operative versus nonoperative management remains controversial, but determining the most effective solution for any given patient depends upon patient-reported outcome measurement (PROM) tools that are able to reliably evaluate the success of a chosen clinical treatment strategy.²⁻⁶

The Achilles Tendon Total Rupture Score (ATRS) is the most commonly used PROM to evaluate outcomes after the treatment of an acute Achilles rupture because it was the first validated, injury-specific PROM.⁶⁻⁸ The Foot and Ankle Ability Measure (FAAM) is used to evaluate a myriad of lower extremity disorders, and has also been shown to have substantial content relevance to patients with Achilles tendon disorders.^{9,10} The more recently developed Patient-Reported Outcomes Measurement Information System (PROMIS) provides a comprehensive set of questionnaires and, critically, items can be administered as a “Computerized Adaptive Test” (CAT) to limit the number of questions that a patient must answer to attain a score. The PROMIS Physical Function (PROMIS PF) CAT has shown to be an excellent method for measuring outcomes for patients with foot and ankle injuries.^{11,12} While all the aforementioned instruments are currently employed to evaluate treatment of lower extremity conditions, the correlation between the validated ATRS, FAAM, and PROMIS PF CAT scores in patients with Achilles tendon ruptures has not been evaluated.¹³⁻¹⁵

The primary aim of this retrospective study was to evaluate the validity, reliability and responsiveness of the PROMIS PF, the FAAM, and the ATRS measurement tools in patients with an acute Achilles tendon ruptures.

Methods

Study design

All adult patients who presented to two academic medical centers with an acute Achilles tendon rupture between 2016 and 2018 were eligible for inclusion. Eligible patients were identified by searching for Current Procedure Terminology (CPT) codes and International Classification of Diseases (ICD) codes in the institution’s Research Patient Data Registry (RPDR). Inclusion criteria were: (1) acute Achilles tendon rupture, (2) 18 years or older, (3) minimum of 12 months follow-up. Exclusion criteria were: (1) treatment for Achilles re-rupture, (2) cognitive impairment,

(3) and language other than English. Data collection was performed by reviewing electronic medical records and, after Institutional Review Board approval, eligible patients were invited to participate in the study by a recruitment letter. Questionnaires were collected online and managed using Research Electronic Data Capture (REDCap).¹⁶

Patient and treatment characteristics

Electronic medical records and collected REDCap questionnaires were reviewed to collect baseline demographic characteristics regarding age, sex, smoking status, other surgery on the affected leg since initial Achilles treatment, trauma mechanism, Charlson Comorbidity Index (CCI), operative treatment method, nonoperative treatment method, and the time from treatment to questionnaire. Smoking status was subdivided into current, former, and never smoker. The CCI is a method of categorizing and indexing multiple comorbidities.¹⁷ Operative treatment included open and minimally invasive/percutaneous surgery. The operative stitch technique was recorded if noted in the operative report and included Bunnell, Kessler, Krackow, End-to-end, Lindholm/Ma-Griffith, and Kessler/Percutaneous. Immobilization methods used included the use of a cast, boot, or splint. The time from initiation of treatment to the start of rehabilitation was collected. Full weight bearing status was divided in less than 4 weeks and 4 weeks or greater. The use of a functional rehabilitation protocol was recorded (e.g. gradual reduction of plantar flexion, self-administered exercise program, or formal physiotherapy) as well as the use of an accelerated rehabilitation protocol (start early range of motion less than 3 weeks).

PROMs

The collection of PROMs was performed electronically and included the PROMIS Physical Function (PF) v2.0 Computerized Adaptive Test (CAT), FAAM Activities of Daily Living (ADL), FAAM Sports, and the ATRS. The PROMIS questionnaires evaluate the limitations of daily activities, pain, and physical activities, with scores ranging from 0 to 100, with higher scores representing higher function, and a mean score of 50 for the general population of the United States.¹⁸ The PROMIS PF CAT was developed using item response theory to maximize efficient administration from a calibrated items bank of 124 question, a minimum number of 4 items must be answered in order to receive a score. The minimal clinical important difference (MCID) of the PROMIS PF CAT is 16 points. The FAAM is developed to assess physical function for individuals with foot and ankle related disabilities, items are scored on a 5-point Likert scale from “no difficulty at all” to “unable to do”, scores are transformed to percentage scores, with higher

scores represent higher levels of functioning.¹⁰ The scores for the FAAM ADL and Sports are regarded valid and generated when subjects complete 90% or more of the items. The MCID of the FAAM ADL/Sports has been reported to be 8 and 9 points, respectively. The ATRS is an instrument developed specifically for measuring outcome after treatment for Achilles tendon ruptures, with items graded on a 11-point Likert scale according to level of limitations and/or difficulties from “major limitations” to “no limitations, with a score of 100 indicating no symptoms and full function.”⁷ The scores for the ATRS are regarded valid and generated when subjects complete 80% or more of the items. The ATRS has a reported MCID of 10 points. Currently, the ATRS has been identified as the most appropriate PROM to evaluate the management of Achilles tendon ruptures, and thus considered to be the primary comparator.^{8,19,20} The time from treatment to questionnaire in months was available for all PROMs. Patients completed all the PROMs questionnaire electronically at the same time, and completed the minimum valid answers required to compute the scores.

Statistical analysis

Descriptive results were presented as mean values with standard deviations and range (SD, range), median values with interquartile range (IQR), or absolute numbers and percentages (%). Pearson’s correlation (r), with 95% confidence interval (CI), was used to assess the relationship between the PROMIS PF, FAAM ADL, FAAM Sports, and the ATRS. Correlation coefficients of 0.3 or less were considered weak, 0.31 to 0.39 as moderate-weak, 0.40 to 0.60 as moderate, 0.61 to 0.69 as moderate-high, and larger than 0.70 as high.²¹ Additionally, floor and ceiling effect were assessed for all PROMs. Absolute floor was defined as the percentage of patients with the absolute lowest possible PROM score, and absolute ceiling as the percentage with the absolute highest possible PROM score. Relative floor was defined as the percentage of patients that reported the lowest PROM score in the cohort, and relative ceiling as the percentage with the highest PROM score reported in the cohort. Floor or ceiling effects are considered to be substantial if more than 15% of patients achieve the lowest or highest possible score, respectively.²² The required sample size for studies assessing measurement properties has been advocated to be a sample size of at least 50 patients.²² The significance level was defined as a p value <0.05 . All analyses were performed in R version 3.6.1 (R Development Core Team, Released 2013, Vienna, Austria: R Foundation for Statistical Computing).²³

Results

Study population

In total, 305 patients met the inclusion criteria, of whom 179 patients (59%) did not respond, and 23 patients (8%) refused participation. This led to the final inclusion of 103 patients (overall response rate of 34%). The different PROMs questionnaires were completed by patients at the same timepoint. The mean time from treatment to PROMs completion was 25.3 months (range 15–36). The patient characteristics, stratified by treatment method, are presented in Table 1.

Treatment method

In total, 82 patients (80%) underwent operative repair. The treatment characteristics are shown in Table 2. Open surgery was performed in 69 patients (86%), with the “Krackow” as most used stitch technique (41%). The median duration of operative treatment to start of rehabilitation was 2.0 weeks (IQR 2.0-5.5). Nonoperative treatment was performed in 21 patients (20%), with “Boot” (48%) used as most common method. The mean duration of nonoperative treatment to start of rehabilitation was 4.5 weeks (IQR 3.0-9.3). The treatment characteristics are shown in Table 2.

Table 1. Characteristics of 103 Achilles tendon rupture patients.

	Overall	Operative	Nonoperative
Patients	103	82	21
Age injury	44.7 (14.6, 19-77)	42.3 (12.9, 19-74)	54.1 (17.2, 25-77)
Sex (%)			
Male	76 (73.8)	63 (76.8)	13 (61.9)
Female	27 (26.2)	19 (23.2)	8 (38.1)
Smoking (%)			
Current	8 (7.8)	6 (7.3)	2 (9.5)
Former	14 (13.6)	11 (13.4)	3 (14.3)
Never	81 (78.6)	65 (79.3)	16 (76.2)
Other surgery on leg since Achilles treatment (%)	7 (6.8)	6 (7.3)	1 (4.8)
Trauma mechanism (%)			
Sports-related	89 (86.4)	73 (89.0)	16 (76.2)
Ground level fall	5 (4.9)	4 (4.9)	1 (4.8)
Fall from height	1 (1.0)	0 (0.0)	1 (4.8)
Twisting motion	5 (4.9)	3 (3.7)	2 (9.5)
Other	3 (2.9)	2 (2.4)	1 (4.8)
CCI index overall	2.0 (1.3, 1-7)	1.8 (1.0, 1-5)	2.7 (1.8, 1-7)
Treatment to PROMs (months)	25.3 (5.7, 15-36)	25.9 (5.7, 15-36)	23.2 (5.1, 16-31)

Continuous variables presented as mean (SD, range); CCI Charlson Comorbidity Index; PROMs patient-reported outcome measures

Table 2. Treatment characteristics of 103 Achilles tendon rupture patients.

Operative treatment	
Patients	82
Operative method (%) (n=80)	
Open surgery	69 (86.2)
Minimally invasive/percutaneous	11 (13.8)
Operative stitch technique (%) (n=59)	
Bunnell	1 (1.7)
Kessler	3 (5.1)
Krackow	24 (40.7)
End-to-end	1 (1.7)
Lindholm/Ma-Griffith	20 (33.9)
Kessler/Percutaneous	9 (15.3)
Other	1 (1.7)
Immobilization method (%)	
Cast	3 (3.7)
Boot	0 (0.0)
Splint	79 (96.3)
Full weight-bearing status (%) (n=80)	
<4 weeks	11 (13.8)
≥4 weeks	69 (86.2)
Time from treatment to rehabilitation (weeks) (n=79)	2.0 (2.0–5.5)
Functional rehabilitation protocol (%) (n=81)	79 (97.5)
Accelerated rehabilitation protocol (%) (n=80)	45 (56.2)
Nonoperative treatment	
Patients	21
Nonoperative method (%)	
Cast	4 (19.0)
Boot	10 (47.6)
Splint	7 (33.3)
Full weight-bearing status (%) (n=18)	
<4 weeks	3 (16.7)
≥4 weeks	15 (83.3)
Time from treatment to rehabilitation (weeks) (n=16)	4.5 (3.0–9.3)
Functional rehabilitation protocol (%) (n=17)	17 (100.0)
Accelerated rehabilitation protocol (%) (n=16)	4 (25.0)
Continuous variables presented as median (IQR)	

PROMs measurement properties

The overall mean PROMs results were PROMIS PF 55.4 (SD 9.2), FAAM ADL 92.9 (SD 12.2), FAAM Sports 77.7 (SD 22.9), and ATRS 83.0 (SD 19.4). The PROMs stratified by treatment method are shown in Table 3. The mutual correlations between the different PROMs are presented in Table 4. The ATRS showed a high correlation with the FAAM ADL (r 0.80; 95%CI 0.72; 0.86; p <0.001) and with the FAAM Sports (r 0.86; 95%CI 0.80; 0.90; p <0.001). PROMIS PF showed a moderate-high correlation with the FAAM ADL (r 0.66; 95%CI 0.53; 0.75; p <0.001), FAAM Sports (r 0.65; 95%CI 0.53; 0.75; p <0.001), and ATRS (r 0.69; 95%CI 0.58; 0.78; p <0.001). The floor and ceiling effects for the PROMs are presented in Table 5. The PROMIS PF did not show absolute floor or ceiling effects (0%). The FAAM ADL (35.9%), FAAM Sports (15.8%), and ATRS (20.4%) had significant absolute ceiling effects. There were no substantial changes in relative floor and ceiling effects compared to the absolute floor and ceiling effects.

Table 3. Patient-reported outcome measures of 103 Achilles tendon rupture patients

	Overall	Operative	Nonoperative
Patients	103	82	21
PROMIS PF	55.4 (9.2)	56.4 (9.1)	51.5 (8.7)
FAAM ADL	92.9 (12.2)	93.6 (11.6)	90.3 (14.5)
FAAM Sports	77.7 (22.9)	78.7 (22.6)	73.5 (24.1)
ATRS	83.0 (19.4)	83.9 (19.5)	79.6 (19.5)

Continuous variables presented as mean (SD); PROMIS Patient-Reported Outcomes Measurement Information System; PF physical function; FAAM Foot and Ankle Ability Measure; ADL Activities of Daily Living; ATRS Achilles Tendon Total Rupture Score

Table 4. Correlations between patient-reported outcome measures of Achilles tendon ruptures

	PROMIS PF	FAAM ADL	FAAM Sports	ATRS
PROMIS PF	–	0.66 (0.53–0.75)	0.65 (0.53–0.75)	0.69 (0.58–0.78)
FAAM ADL		–	0.68 (0.56–0.77)	0.80 (0.72–0.86)
FAAM Sports			–	0.86 (0.80–0.90)
ATRS				–

Correlations are presented as Pearson's correlation with 95% confidence interval (CI); PROMIS Patient-Reported Outcomes Measurement Information System; PF physical function; FAAM Foot and Ankle Ability Measure; ADL Activities of Daily Living; ATRS Achilles Tendon Total Rupture Score. For all correlations $p < 0.001$.

Table 5. Patient-reported outcome measures floor and ceiling effects of Achilles tendon ruptures

	Absolute floor (%)	Absolute ceiling (%)	Relative floor (%)	Relative ceiling (%)
PROMIS PF	0	0	1.0	2.9
FAAM ADL	0	35.9	1.0	35.9
FAAM Sports	0	15.8	1.0	15.8
ATRS	0	20.4	1.0	20.4

Absolute floor/ceiling effect defined as percentage (%) with absolute lowest/highest possible PROM score; Relative floor/ceiling defined as percentage (%) with lowest/highest PROM score reported in cohort; PROMIS Patient-Reported Outcomes Measurement Information System; PF physical function; FAAM Foot and Ankle Ability Measure; ADL Activities of Daily Living; ATRS Achilles Tendon Total Rupture Score

Discussion

In this cohort study of both the operative and nonoperative functional treatment outcome of Achilles tendon ruptures, the FAAM ADL, FAAM Sports, and PROMIS PF all showed a moderate to high mutual correlation with the ATRS. Of these measures, however, it should be noted that only the PROMIS PF CAT avoided substantial floor as well as ceiling effects.

The overall PROMs results from this study demonstrate good to excellent long-term functional outcome following Achilles tendon treatment. The correlation between the ATRS, FAAM, and PROMIS scores in patients with an Achilles tendon rupture has not been previously evaluated. In this study, the ATRS showed a moderate to high correlation with the FAAM ADL, FAAM Sports, and PROMIS PF. The ATRS is an injury specific PROMs, which has been evaluated and found to be valid, reliable, and responsive. It has also been confirmed and validated in several languages, and many currently consider it the most appropriate PROM to evaluate the management of Achilles tendon ruptures.^{8,19,20} Ganestam et al.²⁴ reported the ATRS in 90 patients with a follow up between 2 and 24 months, and showed a moderately strong criterion validity,

with a ceiling effect of 8%. However, the test–retest variability showed poor reliability, raising questions regarding the use of the ATRS for repeated assessments of individual patients.²⁴

Kearney et al.⁸ evaluated 64 patients, and reported the ATRS demonstrated high internal consistency and responsiveness, with a ceiling effect of 11% at 9 months follow-up. The ceiling effect of the ATRS (20.4%) in this study was higher compared to previous reports, which could be due to the shorter follow-up in these studies. Functional outcome is likely to continue to improve with longer follow-up, and the previously reported ceiling effects might have underestimated the actual ceiling effects at long-term follow-up.

The FAAM is used to evaluate a variety of lower extremity disorders, and also demonstrated substantial content relevance to patients with Achilles tendon disorders.^{9,10} While the FAAM has shown to be a reliable, responsive, and valid measure of physical function in various lower extremity disorders, it was validated in 164 individuals with a broad range of musculoskeletal disorders, with only 2 patients sustaining an Achilles tendon rupture. Reb et al.⁹ evaluated the relevance of the FAAM specifically in 75 patients with Achilles tendon disease after a mean of 4 months (range 0–24 months) and concluded a substantial content relevance, however, ceiling effects were apparent for the Sports subscale (42.7%). Subgroup analysis was performed based on treatment groups with ceiling effects for the Sports subscale among nonoperative patients (22%), and ceiling effects for the ADL (21%) and Sports (54%) subscales among operative patients.⁹ These ceiling effects are similar to the results presented in the present study.

The PROMIS has shown to be an excellent method for measuring outcomes for patients with foot and ankle surgery.^{13,14} The PROMIS PF CAT was developed using item response theory to maximize efficient administration from a calibrated items bank of 124 questions and has been shown to results in equally high reliability and less ceiling effects in the assessment of general orthopedic trauma patients.²⁵ Hung et al.¹¹ evaluated the performance of the PROMIS PF CAT specifically for adult patients with common disorders of the foot and ankle, and was found to be an excellent method for measuring outcomes, with a good coverage (floor effect 0%, ceiling effect 0.32%), and an average test administration time of 47 seconds.¹¹ Hung et al.¹² recently also reported the responsiveness of both the PROMIS CAT and FAAM Sports instruments in the orthopedic foot and ankle population, which including 785 patients and found both to be sensitive and responsive to changes in patient-reported functional health. However, the study included a variety of 43 different disorders without further specifying whether they included

Achilles tendon ruptures.¹² They stated that further assessment of the responsiveness of the PROMIS and FAAM Sports instruments within specific conditions and across different populations is recommended.¹²

The PROMIS questionnaires were developed with the goal of providing standardized, valid, and flexible PROMs collection tools with features that lower response burden and make it possible to seamlessly incorporate them into patients' medical record.^{13-15,26} Papuga et al.²⁶ recently explored the implementation of PROMIS CAT tools with 23,813 patient during outpatient clinics visits and reported an average time to completion of 3.5 minutes. There was no significant change in registration times for new patients, showing the implementation of PROMIS to be effective; results, moreover, could be imported directly into the electronic medical record in real time for use during the clinical visit.²⁶ Ho et al.²⁷ assessed whether preoperative PROMIS PF CAT scores were predictive of functional improvement after operative treatment in foot and ankle patients. They found that patients with scores below 29.7 were likely to improve with surgery, whereas patients with scores above 42 were unlikely to improve.²⁷ Cutoff values like these could help guide surgeons regarding the most appropriate treatment option for each individual patient. Future research could focus on reporting the prognostic cutoff values of the PROMIS PF CAT scores for Achilles tendon ruptures. The PROMIS instruments are already being used in the evaluation of Achilles tendon disorders.^{28,29}

PROMs are increasingly used in orthopedic trauma care to evaluate patient-oriented health status in clinical care and research, to assess cost-effectiveness, and, more recently, to influence reimbursement decisions. Today, however, a number of different outcome measures are still used in different Achilles tendon studies.^{19,20} Despite early promising results, PROMIS has not been adopted in most orthopedic literature. The performance of the PROMIS compared to various legacy "traditional" outcome measures has been evaluated across various conditions which have shown the PROMIS to correlate well with traditional outcome measures used in orthopedic studies.¹³⁻¹⁵ Validity, reliability, and responsiveness are properties that define the clinical relevance of any outcome instrument, and establishing usefulness is an ongoing process meant to substantiate utility under various conditions and populations.²⁰ These properties may differ across settings and patient populations. It is therefore important to continue to evaluate different available PROMs in specific patient populations. The correlations found in this study suggest that perhaps PROMIS PF CAT ought to be considered the most useful measure for evaluating

patients with an Achilles tendon rupture—particularly when compared to the use of FAAM or ATRS. The PROMIS PF CAT tool did not show substantial floor or ceiling effects, while both the FAAM and the ATRS showed substantial (>15%) ceiling effects. Such effects suggest that extreme items are missing in the upper end of the FAAM and ATRS outcome instruments, indicating limited content validity. Therefore, patients with the highest possible score cannot be distinguished, thus reducing reliability. Furthermore, responsiveness is limited as functional changes cannot be measured in these patients.²² This might presents challenges in studies that explore and evaluate improvement in the more athletic patients with Achilles tendon ruptures.

Potential limitations in this study need to be acknowledged. First, the study is limited by the nature of the injuries in a trauma setting, hence we were unable to collect PROMs at the time of injury to allow for baseline comparison. Second, only 103 patients contacted (34%) ultimately participated in this study, potentially creating selection bias among those that did agree. Third, the study might be limited by the order in which the PROMs were administered to patients during the electronically collection. Randomization of the order of the PROMs questionnaires may have eliminated the potential effects of survey fatigue. Finally, the different PROMs were only evaluated in the English language.

Conclusion

The PROMIS PF, FAAM ADL, and FAAM Sports all showed a moderate to high mutual correlation with the ATRS. However, of these measures, only the PROMIS PF CAT avoided substantial floor or ceiling effects. The results of this study strongly suggest that PROMIS PF CAT be considered perhaps the most valid and responsive tool for evaluating function after Achilles tendon rupture—regardless of whether patients are treated operatively or non-operatively.

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