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Feasibility, Reliability, Responsiveness, and Validity of the Patient-Reported Functional Scale for the Intensive Care Unit: A Pilot Study

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Abstract

Background: Although many performance-based measures assess patients' physical function in intensive care unit (ICU) survivors, to our knowledge, there are no patient-reported ICU rehabilitation-specific measures assessing function. We developed the Patient-Reported Functional Scale-ICU (PRFS-ICU), which measures patients' perceptions of their ability to perform 6 activities (rolling, sitting edge of bed, sit-to-stand and bed-to-chair transfers, ambulation, and stair climbing). Each item is scored from 0 (unable) to 10 (able to perform at pre-ICU level) to a maximum of 60. **Objectives:** Estimate the feasibility, reliability, responsiveness, and validity of the PRFS-ICU. **Methods:** This was a substudy of TryCYCLE, a single-center, prospective cohort examining the safety and feasibility of early in-bed cycling with mechanically ventilated patients (NCT01885442). To determine feasibility, we calculated the number of patients with at least 1 PRFS-ICU assessment during their hospital stay. To assess reliability, 2 raters blinded to each other's assessments administered the PRFS-ICU within 24-hours of each other. We calculated the intraclass correlation coefficient (ICC; 95% confidence interval [CI]), standard error of measurement (SEM, 95% CI), and minimal detectable change (MDC_{90}). To assess validity, we estimated convergent validity of the PRFS-ICU with the Functional Status Score for ICU (FSS-ICU), Medical Research Council Sum Score (MRC-SS), Physical Function Test for ICU (PFIT-s), Katz Index of Independence in Activities of Daily Living (Katz ADLs), and a pooled index using Pearson's correlation coefficient (*r*, 95% CI). **Results:** Feasibility: 20 patients completed a PRFS-ICU assessment. Reliability and responsiveness: 16 patients contributed data. The ICC, SEM, and MDC_{90} were 0.91 (0.76, 0.97), 4.75 (3.51, 7.35), and 11.04 points, respectively. Validity: 19 patients contributed data and correlations were (*r* [95% CI]): FSS-ICU (0.40 [−0.14, 0.76]), MRC-SS (0.51 [0.02, 0.80]), PFIT-s (0.43 [−0.13, 0.78]), Katz ADLs (0.53 [0.10, 0.79]), and pooled index (0.48 [−0.14, 0.82]). **Conclusions:** Our pilot work suggests the PRFS-ICU may be a useful tool to assess and monitor patients' perceptions of function over time.

Keywords

intensive care unit, outcome measure, patient-report, physical function, reliability, validity

Introduction

With advances in medical technology, more people are surviving critical illness,[1] and interest in physical rehabilitation interventions to minimize these impairments is growing.[2,3] To determine the impact of physical rehabilitation on improving functional outcomes, it is essential to use reliable and valid outcome measures.[4] To date, there are few physical function measures developed specifically for patients with critical illness[5] and none to our knowledge that assess their perceptions of function in the acute care setting.

Given today's focus on patient-centered care, we need to consider what is meaningful to patients across the continuum of their recovery and incorporate patient-reported measures in rehabilitation evaluations.[6] A systematic review identified 47 studies and 33 different physical outcome measures in

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patients with critical illness.[7] Of 26 that assessed physical function, only 6 were developed for the intensive care unit (ICU) setting, all were performance based, and none were reported by patients. More recently, a systematic review[8] and a prospective cohort of patients with acute respiratory distress syndrome[9] described the use of generic (eg, Short-Form 36 [SF-36],[10] Euro-Qol-5[11]) and disease-specific (3-Set 4P[12]) measures reported by patients. However, the 3-SET 4P is completed posthospital discharge and is used to identify the needs of critically ill patients during their post-ICU recovery.[12] We identified no ICU rehabilitation-specific patient-reported outcomes developed for use during an acute hospital stay.[8,9]

To address the specific needs of patients with critical illness, we developed the *Patient-Reported Functional Scale-ICU* (PRFS-ICU). The objective of this study was to assess the feasibility of administering the PRFS-ICU to critically ill patients in the acute care setting and to estimate its reliability, responsiveness, and convergent validity.

Methods

Design

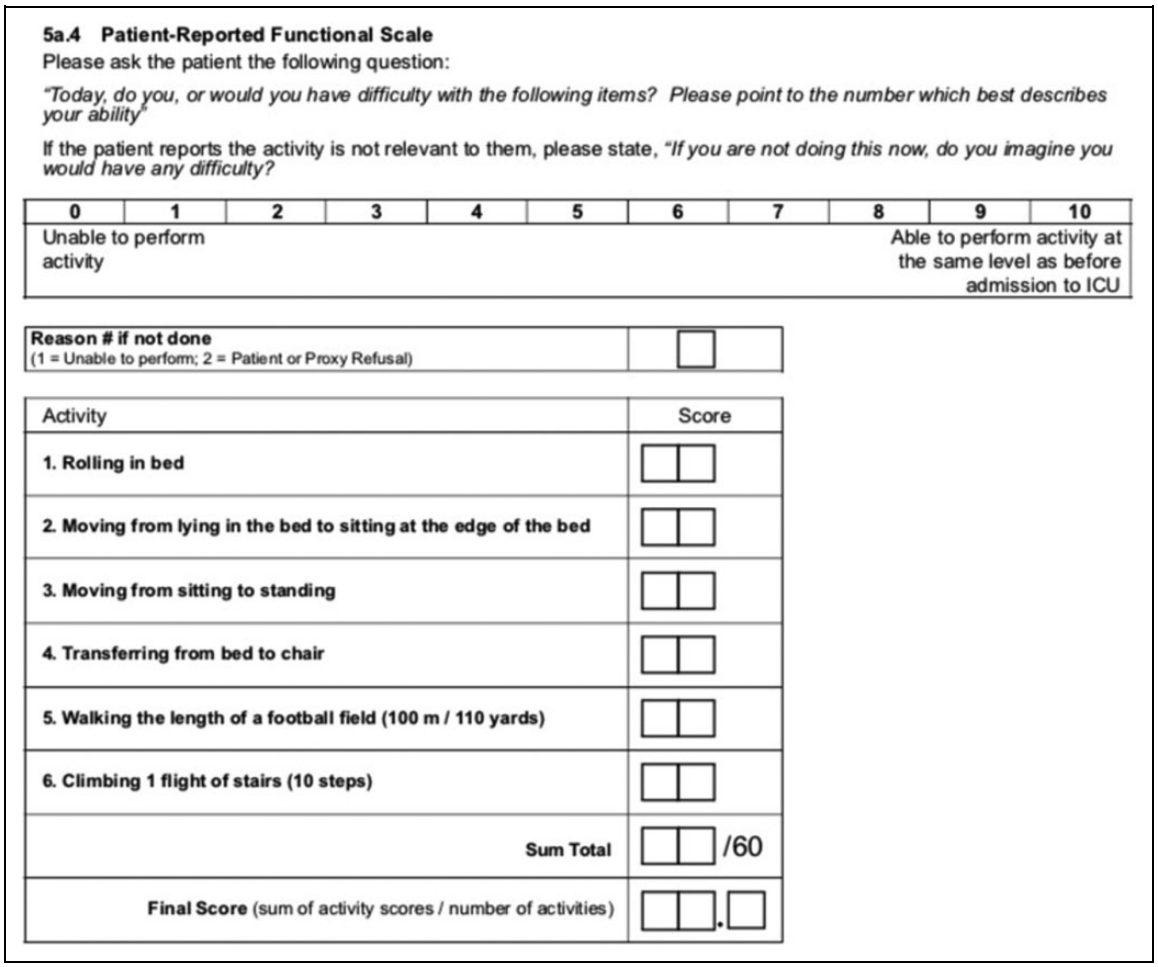
Instrument development. We developed the PRFS-ICU based on 2 existing instruments, the Patient-Specific Functional Scale (PSFS) and the Functional Status Score for ICU (FSS-ICU). The PSFS is a reliable and valid patient-reported measure, primarily used in the outpatient setting in patients with knee dysfunction, cervical radiculopathy, low back pain, and neck dysfunction.[13] The PSFS asks patients to self-select up to 5 important activities, where they experience difficulty as a result of their condition.[14] Patients rate activities on an 11-point scale from 0 (unable to perform) to 10 (able to perform at preinjury level).[14] The FSS-ICU is a performance-based measure assessing 5 functional items including rolling in bed, sitting at the edge of the bed, sit-to-stand and bed-to-chair transfers, and ambulation.[15] The FSS-ICU has excellent reliability and validity in ICU patients.[16,17] The PRFS-ICU (Figure 1) combines the 11-point PSFS scale with the items from the FSS-ICU, plus 1 additional item, stair climbing. In the PRFS-ICU, patients rate each of the 6 items on an 11-point scale (0—unable, 10—able to perform at pre-ICU level) with a maximum possible score of 60 (higher scores represented better perceived function). The scale can be administered in a hypothetical manner, and patients are not required to perform the activities to provide a response. The instructions if administered hypothetically are as follows: "If you are not doing this now, do you imagine you would have any difficulty?." The PRFS-ICU differs from the PSFS because it prespecifies the activities; it differs from the FSS-ICU because it is a patient-reported measure, rather than a performance-based measure.

Participants. We nested this study of the psychometric properties of the PRFS-ICU within a single-center, prospective pilot study examining the safety and feasibility of early in-bed cycling for mechanically ventilated (MV) patients (TryCYCLE, NCT01885442).[18] We enrolled MV adult patients (>18 years of age) from a 21-bed academic medical–surgical ICU in Hamilton, Ontario, Canada. Screening occurred at ICU admission and patients who were MV $\leq$4 days, had been in ICU $\leq$7 days, and who ambulated independently (with or without a gait aid) before hospitalization were eligible for inclusion in TryCYCLE. Exclusion were inability to follow commands in English, acute condition impairing the patient's ability to cycle (eg, leg fracture), neuromuscular weakness affecting the legs (eg, stroke), temporary pacemaker, expected hospital mortality >90%, body habitus unable to fit the bike, pregnancy, palliative goals of care, and cycling exemptions precluding cycling within the first 4 days of MV.[18] A research coordinator obtained written informed consent from all participants or their substitute decision maker. The Hamilton Integrated Research Ethics Board approved TryCYCLE.

Measures. Research coordinators administered the PRFS-ICU scale at 3 time points: ICU awakening, ICU discharge, and hospital discharge. Research coordinators facilitated patients' completion of the measure (ie, by reading instructions and tasks and eliciting patient responses) if needed. We also assessed the following 4 performance-based measures at the same time points: Functional Status Score for ICU (FSS-ICU),[15] Medical Research Council Sum Score (MRC-SS),[19] Physical Function Test for ICU-scored (PFIT-s),[20] and the Katz Index of Independence in Activities of Daily Living (Katz ADLs).[21] We conducted ICU awakening assessments once patients could follow 3 of 5 simple commands (open your eyes, look at me, open your mouth and stick out your tongue, nod your head, and raise your eyebrows when I count to 5).[22] We conducted all assessments during typical daytime working hours. Table 1 provides an overview of each functional measure.

Physiotherapists administered the FSS-ICU, MRC-SS, and PFIT-s, and research coordinators administered the PRFS-ICU and Katz ADLs. All outcomes assessors received standardized training and written materials on the administration and scoring of each measure. For multipart measures (eg, PFIT-s), we scored items "0" if an item was not attempted due to pain, lines interfering with specific components of an assessment (eg, intravenous or arterial catheters, wound drains, and so on, crossing a joint that would impede evaluation), amputation, and so on or if the assessor perceived the patient was unable to perform the item due to safety concerns.

Feasibility. We assessed PRFS-ICU administration feasibility by calculating the number of patients for whom we recorded at least 1 measure during their acute care stay. We classified missing assessments into 1 of the following 2 reasons: (1) unable to follow commands and (2) assessment missed. Post hoc, we reviewed medical records to collect data on intubation status to evaluate potential effects on feasibility. We considered all patients who passed the awakening and comprehension screen (following 3 of 5 commands[22]) to be eligible for an ICU awakening assessment and all patients who were alive at ICU



5a.4 Patient-Reported Functional Scale

Please ask the patient the following question:

"Today, do you, or would you have difficulty with the following items? Please point to the number which best describes your ability"

If the patient reports the activity is not relevant to them, please state, *"If you are not doing this now, do you imagine you would have any difficulty?*

0	1	2	3	4	5	6	7	8	9	10
Unable to perform activity										Able to perform activity at the same level as before admission to ICU

Reason # if not done (1 = Unable to perform; 2 = Patient or Proxy Refusal)	

Activity	Score
1. Rolling in bed	
2. Moving from lying in the bed to sitting at the edge of the bed	
3. Moving from sitting to standing	
4. Transferring from bed to chair	
5. Walking the length of a football field (100 m / 110 yards)	
6. Climbing 1 flight of stairs (10 steps)	
Sum Total	/60
Final Score (sum of activity scores / number of activities)	.

Figure 1. Patient-Reported Functional Scale for ICU. ICU indicates intensive care unit.

and hospital discharge to be eligible for an assessment at those points.

Reliability and responsiveness. Two research coordinators, blinded to each other's assessment results, administered the PRFS-ICU within 24 hours of each other. Patients with at least 1 paired assessment were included in the reliability and responsiveness analysis. If patients had a paired assessment for more than 1 time point, we included the earliest paired assessment such that each patient was represented for only 1 time point in the analysis. We also assessed the PRFS-ICU for floor and ceiling effects using patients' first score from the reliability analysis.

Validity. We developed a hierarchical approach to include individual outcome measures in the validity analysis. We first identified all patients with a PRFS-ICU score and at least 1 of the 4 functional measures (FSS-ICU, MRC-SS, PFIT-s, and Katz ADLs) completed within 3 days of the PRFS-ICU at any time point. We selected a 3-day interval because it would be unlikely for any significant changes in strength or function to occur within this time frame. We excluded a measure from the validity analysis if a patient did not attempt any part of the assessment (eg, patient or proxy refusal).

We included each patient only once in the validity analysis. We used the following method to determine which outcome measures were included: If a patient had all 4 functional measures completed at the same time point, we included all outcomes from that time point. If a patient had all 4 measures completed at more than 1 time point, we randomly selected 1 time point for inclusion by drawing numbers from a hat. For patients who did not have all 4 measures completed at 1 time point, but had at least 1 measure for more than 1 time point (eg, FSS-ICU within 3 days of the PRFS-ICU at ICU awakening and ICU discharge), we randomly selected 1 time point for inclusion as described earlier. We repeated this method for all outcome measures by patient.

Statistical Analyses

We computed descriptive statistics of continuous variables as means and standard deviations (SD) or medians and first and third quartiles (first, third) if data were skewed. For categorical variables, we calculated counts and percentages. We completed

Table 1. Overview of Measures Included in the Validity Assessment.

Measure	Description	Scores	Reliability and Responsiveness	Validity
FSS-ICU[15]	Assesses 5 functional tasks (rolling, transfer supine to sit, sitting at edge of bed, transfer sit to stand, ambulation). Each item scored from 0 (unable to perform) to 7 (able to perform independently)	Total score/35 Higher scores indicate better function	0.99[16] SEM: 1.3-2.4 MDC: 3.1-5.4[17]	Correlation with Katz ADLs: $r = 0.48$[17] Correlation with MRC-SS: $r = 0.81$[17]
MRC-SS[19]	Overall measure of muscle strength in 6 major muscle groups bilaterally in upper and lower extremities. Each item scored from 0 (no visible or palpable contraction) to 5 (normal power)	Total score/60 Higher scores indicate better strength	0.83 (testing occurred in ICU, n = 10 and on the ward, n = 20)[31] – 0.95 (all testing occurred in ICU, n = 75)[19]	Correlation with maximum hand grip strength: $r = 0.50$[30]
PFIT-s[20]	4 items assessing upper and lower extremities strength, assistance required for sit to stand, marching on the spot cadence. Each item scored from 0 (grade 0, 1, 2 strength; unable to stand or march on the spot) to 3 (grade 5 strength; no assistance required to stand, 80+ steps marching cadence)	Total score/12 (ordinal scale); /10 (interval scale) Higher scores indicate better function	0.99[33] MCID: 1.5/10 points[20]	Correlation with 6MWT: $r = -0.60$[20] Correlation with MRC-SS: $\rho = .49$[20]
Katz ADLs[21]	Assesses independence with 6 ADLs (bathing, dressing, toileting, transferring, continence, feeding). Each item scored from 0 (dependent) to 1 (independent)	Independence = 1, dependence = 0. Total score/6 Higher scores indicate more independence	Not established[7]	Correlation with SF-36 physical score at 1-month post-ICU discharge: any impairment in ADLs associated with decreased quality of life[34]

Abbreviations: ADLs, activities of daily living; FSS-ICU, Functional Status Score for ICU; ICU, intensive care unit; MDC, minimal detectable change; MRC-SS, Medical Research Council Sum Score; MCID, minimal clinically important difference; 6MWT, six-minute walk test; PFIT-s, Physical Function Test for ICU-scored; SEM, standard error of measurement; SF-36, Short-Form 36.

visual inspection of descriptive data by boxplots and histograms, and assessed normality using the Shapiro-Wilk test.

Feasibility. We calculated descriptive statistics for the number of assessments completed and the reasons assessments were not done.

Reliability. Given the potential for both rater and patient influences on PRFS-ICU scores, our estimation of reliability incorporated components of both interrater reliability and test–retest reliability. We calculated the intraclass correlation coefficient (ICC) using a 2-way random-effects model (Shrout and Fleiss 2,1 ICC [95% confidence interval or CI][23,24]). This model represents a more conservative approach for estimating ICC, as it accounts for random variation from a larger population.[25] We also calculated the standard error of measurement (SEM; 95% CI)[24] and the minimal detectable change score (90% confidence [MDC_{90}]).[23] For floor and ceiling effects, we assessed the distribution of scores across the scale using counts and percentages.

Validity. We assessed convergent validity by comparing the PRFS-ICU with performance-based measures of function including the FSS-ICU, MRC-SS, PFIT-s, and Katz ADLs. Convergent validity assesses the degree to which 2 measures of related constructs are in fact related.[23] We correlated the PRFS-ICU with performance measures of function, which assess different but related aspects of physical functioning (ie, patients' perceptions of function vs actual functional performance). Because we compared patient-reported to performance-based measures, we expected moderate correlation values.[26-28]

We completed visual inspections of each measure using scatter plots. We assessed normality and homoscedasticity using the multivariable test for normality and the Breusch-Pagan tests, respectively. We conducted correlation analyses using Pearson's correlation coefficient (r) with 95% confidence limits. To summarize the available data for each of the 4 measures, we conducted a pooled index analysis by transforming the scores of each measure to a common scale and produced a sum score,[29] which we then correlated with the PRFS-ICU. We conducted all analyses using Stata (version 14.2; StataCorp LP, College Station, Texas).

Results

Between October 30, 2013, and August 18, 2014, we enrolled 33 patients in TryCYCLE.[18] Figure 2A and 2B outlines patient inclusion for the reliability and validity analyses, respectively.

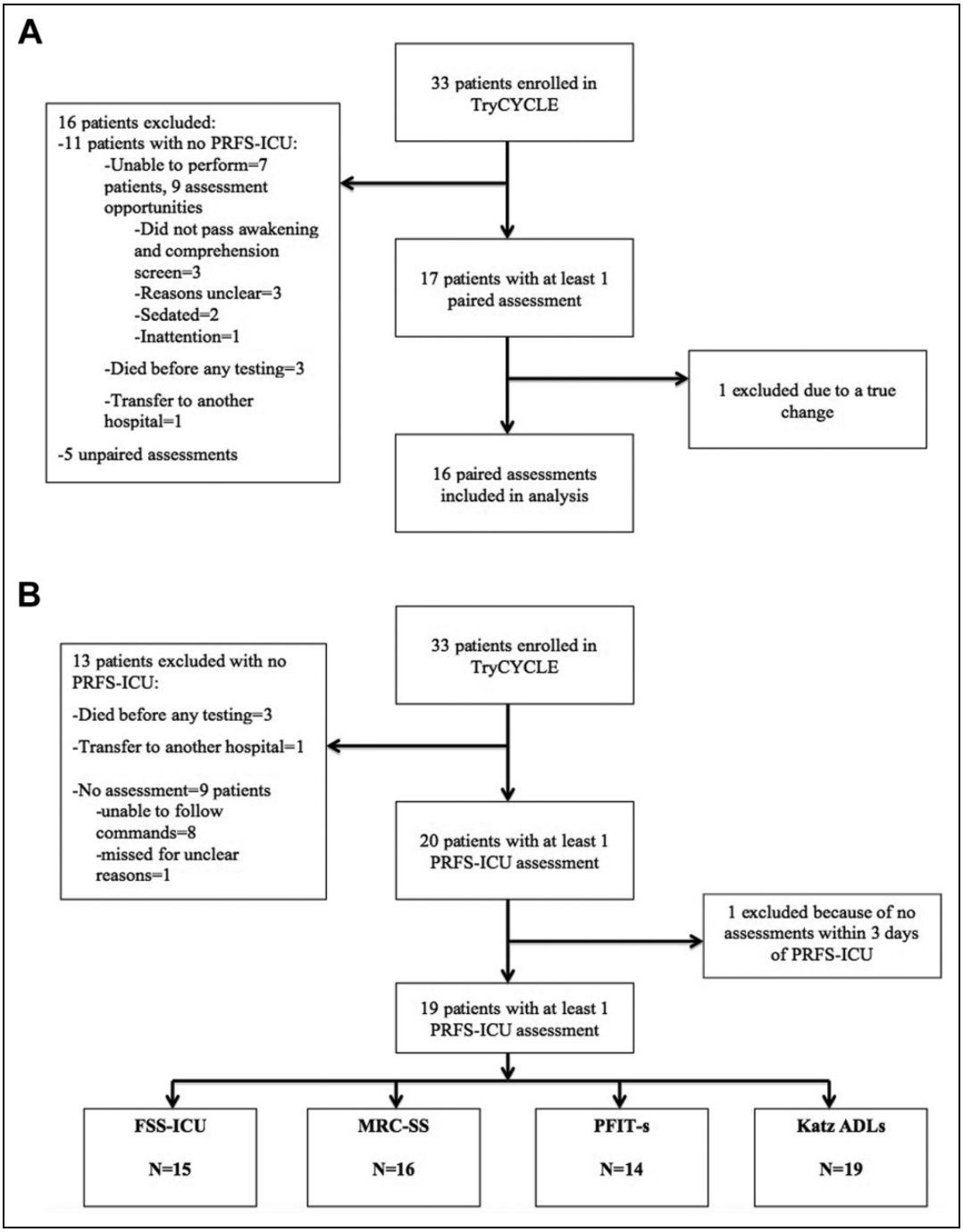


Figure 2. A, Patient flow diagram for inclusion in the reliability analysis. We included only patients who had paired PRFS-ICU assessments at any time point and did not exhibit a true change in the 24-hour reassessment period. B, Patient flow diagram for inclusion in the validity analysis. We included only patients who had a functional measure occurring within 3 days of the PRFS-ICU assessment. FSS-ICU indicates Functional Status Score for ICU; MRC-SS, Medical Research Council Sum Score; PFIT-s, Physical Function Test for ICU-scored; ADLs, activities of daily living.

Feasibility

Twenty (61%) patients completed at least 1 PRFS-ICU assessment and contributed data to one or both analyses. We were not able to determine the influence of intubation status on PRFS-ICU administration because precise extubation times were not consistently reported in the patient chart.

Reliability

Seventeen patients had 1 or more paired PRFS-ICU assessments for at least 1 time point; we excluded 1 patient due to change to palliative goals of care between the 2 assessments (Figure 2A). Of the 16 included patients, nearly all (94%) had a medical diagnosis and had a mean (SD) Acute Physiology and

Table 2. Demographics and Baseline Variables for Patients Included in the Reliability and Responsiveness Analysis (n = 16).

Patient Demographics (N = 16)	
Age, years, mean (SD)	66.8 (11.3)
Sex (male), n (%)	10 (62.5)
Medical admission, n (%)	15 (93.8)
APACHE II score, mean (SD)	24.5 (5.8)
Charlson Comorbidity Index, median (first, third quartiles)	2 (1, 3.5)
Functional Comorbidity Index, mean (SD)	2.3 (1.5)
Pre-ICU Katz Activities of Daily Living Score, median (first, third quartiles)	6 (5, 6)
Pre-ICU Functional Status Score for ICU, median (first, third quartiles)	35 (33.5, 35)
ICU length of stay, median (first, third quartiles)	10 (7, 12.5)
ICU mortality, n (%)	0 (0)
Hospital length of stay, median (first, third quartiles)	32.5 (17.5, 49.5)
Hospital mortality, n (%)	2 (12.5)

Abbreviations: APACHE, Acute Physiology and Chronic Health Evaluation; ICU, intensive care unit; SD, standard deviation.

Table 3. Demographics and Baseline Variables for Patients Included in the Validity Analyses (n = 19).

Patient Demographics (N = 19)	
Age, years, mean (SD)	65.62 (10.76)
Sex (male), n (%)	10 (52.6)
Medical Admission, n (%)	17 (89.5)
APACHE II Score, mean (SD)	23.79 (5.04)
Charlson Comorbidity Index, mean (SD)	2.16 (1.80)
Functional Comorbidity Index, mean (SD)	2.32 (1.29)
Pre-ICU Katz Activities of Daily Living Score, median (first, third quartiles)	6 (5, 6)
Pre-ICU Functional Status Score for ICU, median (first, third quartiles)	35 (34, 35)
ICU length of stay, median (first, third quartiles)	11 (6, 13)
ICU mortality, n (%)	0 (0)
Hospital length of stay, median (first, third quartiles)	24 (16, 44)
Hospital mortality, n (%)	3 (15.8)

Abbreviations: APACHE, Acute Physiology and Chronic Health Evaluation; ICU, intensive care unit; SD, standard deviation.

Chronic Health Evaluation (APACHE) II score of 25 (6). All patients had independent function prehospital admission with median (first, third) FSS-ICU and Katz ADLs scores of 35 (34, 35) and 6 (5, 6), respectively. Table 2 summarizes the baseline characteristics of patients included in the reliability analysis. The median (first, third) score for the first PRFS-ICU assessment was 29 (18, 35), and the retest assessment (within 24 hours) score was 28 (19, 42). The estimated ICC (95% CI) was 0.91 (0.76, 0.97) and the SEM (95% CI) was 4.75 (3.51, 7.35) points. Responsiveness, as defined by MDC_{90}, was 11.04 points. No patients reported a score of 0/60, and 1 (6.3%) patient reported a score of 60/60.

Validity

Of the 20 patients with a PRFS-ICU assessment, 19 had a functional measure occurring within 3 days of the PRFS-ICU assessment and were included in the analysis (Figure 2B). Seven (36.8%) patients completed functional assessments on the same day as the PRFS-ICU, with the remaining 12 patients completing assessments at 1 day (5, 26.3%), 2 days (3, 15.8%), and 3 days (4, 21.1%), respectively. Ninety percent of the patients had a medical diagnosis and had a mean (SD) APACHE II score of 24 (5). All patients had independent function prehospital admission with median (first, third) FSS-ICU and Katz ADLs scores of 35 (34, 35) and 6 (5, 6), respectively. Table 3 summarizes the baseline characteristics of patients included in the validity analysis.

We represented patients only once in each correlation analysis. By outcome, 15, 16, 14, and 19 patients contributed to correlations between the PRFS-ICU and FSS-ICU, MRC-SS, PFIT-s, and Katz ADLs, respectively. We report mean (SD) scores for each measure, mean (SD) scores of the PRFS-ICU for each analysis, and correlation results in Table 4. All point estimates of Pearson's correlation coefficients were 0.40 or higher. The pooled index analysis demonstrated a Pearson's correlation (95% CI) of 0.48 (−0.14, 0.82) with the PRFS-ICU.

Table 4. Summary Statistics and Validity Analyses of the PRFS-ICU With FSS-ICU, MRC-SS, PFIT-s, and Katz ADLs.

Measure	N	Score (SD)/Total	PRFS-ICU (SD)/60	Pearson *r* Correlation (95% CI)
FSS-ICU	15	27.5 (5.9)/35	35.1 (14.2)	0.40 (−0.14, 0.76)
MRC-SS	16	52.1 (5.1)/60	34.6 (14.7)	0.51 (0.02, 0.80)
PFIT-s	14	8.4 (2.3)/12	34.1 (15.9)	0.43 (−0.13, 0.78)
Katz ADLs	19	2.1 (2.3)/6	33.0 (14.7)	0.53 (0.097, 0.79)

Abbreviations: ADLs, activities of daily living; CI, confidence interval; FSS-ICU, Functional Status Score for ICU; MRC-SS, Medical Research Council Sum Score; PFIT-s, Physical Function Test for ICU-scored; SD, standard deviation.

Discussion

In this pilot study of patients with critical illness, administration of the PRFS-ICU was feasible with those patients able to follow verbal commands, demonstrated high reliability, a low SEM of 5 of 60 points, and was responsive with an 11-point difference indicating true change. The PRFS-ICU demonstrated moderate correlations with the MRC-SS and Katz ADLs. To our knowledge, we are the first to develop and report a patient-reported measure for ICU patients in the acute-care setting.

We identified 1 existing patient-reported measure developed specifically for ICU patients—the 3-SET 4P.[12] However, the purpose of this measure was to assess ICU survivors' need for follow-up 2 months post-ICU discharge and was not intended for administration in acute care.[12] Other patient-reported measures such as the SF-36[10] and Euro-QOL-5[11] are generic and were not developed to meet the specific needs of ICU survivors. In contrast, the PRFS-ICU is specific to patients

with critical illness and elicits their perceptions of function in the acute care setting. Patients in the ICU have unique characteristics, such as illness severity and dynamic issues such as level of sedation, cognition, and delirium,[30] which pose challenges to develop and assess outcome measures for this population. With the potentially high levels of functional disability typically associated with critical illness, patients may have limited ability to identify specific and realistic functional goals, which is a requirement for measures such as the PSFS. The PRFS-ICU addresses this issue by prespecifying progressive mobility activities that are necessary to the recovery of physical function.

The PRFS-ICU was feasible in patients with critical illness who were awake and able to follow simple commands. Our PRFS-ICU completion rate of 61% was comparable or better than common ICU performance-based measures with reported completion rates for manual muscle testing varying from 31%[27] to 69%.[26] Some of the most common outcome measures with critically ill patients in the ICU, such as manual muscle testing, identified important administration challenges.[30,31] Issues such as patient inattention,[15,30,31] injury impeding assessment in 6 or more muscle groups,[31] or lack of assessor availability[15] are all barriers to conducting these measures. We encountered challenges with PRFS-ICU administration due to inability to follow commands similar to the above studies. Thus, the feasibility of conducting outcome measures is an important consideration for this population.

Although patient-reported measures are similarly vulnerable to participation barriers as performance-based measures, the specific challenges may differ. Patient-reported measures are not restricted by limitations such as pain, lines/tubes, or injury. Conversely, intubation status and ability to verbalize responses may impair conduct of patient-reported measures. Of the 33 patients enrolled in TryCYCLE, 4 died or were transferred to another hospital. Nine (31.0%) of the remaining 29 patients did not complete a PRFS-ICU due to inability to follow commands or missed assessments. For these patients, we considered 2 potentially modifiable factors to improve outcome completion, including minimizing sedation and optimizing factors to reduce the risk of confusion and delirium. We did not formally evaluate sedation status or delirium in these patients at the time of PRFS-ICU administration. Oral intubation may also influence administration of a patient-reported measure, although we did not collect intubation status at the time of assessment. This could be overcome by introducing the use of alternative and augmentative devices such as letter, number, or picture boards, or providing pen and paper for patients to write.[32] Given the potential barriers in this population, it is likely that a suite of measures, rather than a single one would provide the best picture of a patient's function. Therefore, the PRFS-ICU is an excellent complement to other performance-based measures of function.

The PRFS-ICU demonstrated excellent interrater reliability in our sample (ICC = 0.91). Our interrater reliability is comparable with other performance-based measures such as the FSS-ICU (ICC = 0.99)[16] and the PFIT-s (ICC = 0.99).[33] The PRFS-ICU is also responsive with an 11/60-point difference between assessments indicating true change. The FSS-ICU has an MDC_{90} of 3 to 5 out of 35 points[17] and the PFIT-s has a minimal clinical important difference of 1.5/10 points.[20] Across all 3 outcomes, these differences represent <20% of their scales to demonstrate true and important change. Our assessment of floor and ceiling effects determined no patient reported 0/60 and 1 patient reported a 60/60, indicating a 6.3% ceiling effect.

Our validity analysis demonstrated moderate correlations between the PRFS-ICU and the MRC-SS and Katz ADLs. Because there are no other known patient-reported measures for use with ICU patients in acute care, we conducted our validity analysis with performance-based measures. We anticipated moderate correlations and our results are consistent with other studies evaluating correlations between self-report and performance-based measures. In studies of patients with hip and hand osteoarthritis,[26] correlation of self-report and performance-based measures varied from 0.32 to 0.52[26] and 0.37 to 0.67,[27] respectively. Our results suggest that the PRFS-ICU may be useful, in conjunction with other performance-based measures, to assess patients' function over time.

Limitations and Strengths

Our study has limitations. We included a convenience sample of patients enrolled in a clinical trial. Twenty patients completed at least 1 PRFS-ICU assessment. As a result, we had small sample sizes for each analysis, which may have led to an overestimation or underestimation of our ICC and correlation values. Small sample sizes also limit the generalizability of results. For 9 patients, we were not able to ascertain why they did not complete a PRFS-ICU assessment due to limited documentation such as "unable to perform" or "patient or proxy refusal." In our validity analysis, we allowed up to 3 days for patients to complete the PRFS-ICU and the functional assessments; while no physical functional change was likely to occur during this time, patients' perceptions could have changed. In future, it would be ideal for patients to complete the PRFS-ICU and the physical function assessments on the same day. Finally, with no other known patient-reported measures for use with this population in this clinical setting, and no gold-standard performance-based measure of function in the ICU, we conducted our correlation analyses with a mix of performance-based measures (Table 1).

Our study has several strengths, including being the first, to our knowledge, to assess patients' perceptions of their functioning in the acute care setting. All professionals involved in administering the physical function measures were specifically trained to conduct these assessments. With standardized instructions and training materials for the PRFS-ICU, we ensured consistency in administration between raters and patients. Raters conducted the paired PRFS-ICU assessments blinded to each other's scores within 24 hours, making it unlikely that any substantial change in patient status occurred.

We included all of the correlating functional measure assessments within 3 days of the PRFS-ICU as we did not expect significant functional or strength changes over that period.

Future Research

Future research should include larger sample sizes. Based on an expected correlation of 0.50 from our pooled analysis results, with α set at .05 and 80% power, 395 patients are needed to confirm our preliminary findings. The second target is to better understand potentially modifiable factors for PRFS-ICU administration by providing more specific response options documenting reasons why patients are unable to perform an assessment.

Conclusion

In this pilot study, the PRFS-ICU holds promise as a clinically useful outcome measure that moderately correlates with measures of strength and ADL. It is feasible to administer to critically ill patients who can follow commands in an acute care setting. If a patient's score changes by 11 points between assessments, it is likely that a true change in functional status occurred. To assess and monitor patients' perceptions of function over time, the PRFS-ICU could be further evaluated in future research in the acute care setting.

Author's Note

Michelle E. Kho, Deborah J. Cook, and France Clarke designed the study; Michelle E. Kho, France Clarke, Alexander Molloy, and Julie Reid collected the data; Julie Reid, Michelle E. Kho, and Paul Stratford conducted the statistical analysis; Julie Reid and Michelle E. Kho interpreted the data and wrote the manuscript; and France Clarke, Deborah J. Cook, Alexander Molloy, Paul Stratford, and Jill Rudkowski all contributed to interpret the data. All authors read and approved the manuscript. Data supporting the findings are available and can be requested from the corresponding author.

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Declaration of Conflicting Interests

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