Psychometric Properties of the Patient-Reported Outcomes Measure of Pharmaceutical Therapy for Quality of Life (PROMPT-QOL)

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A B S T R A C T

Objectives: To assess the psychometric properties of a novel instrument for medication management, the Patient-Reported Outcomes Measure of Pharmaceutical Therapy for Quality of Life (PROMPT-QOL), using both conventional psychometrics and Rasch analysis in a large sample. **Methods:** This study was conducted with 1156 adult outpatients continuously taking any medicines at least 3 months from three university hospitals in Bangkok, Thailand, between July 2014 and March 2015. The psychometric properties were assessed in five steps: 1) assessment of dimensional structure, 2) item selection, 3) assessment of practicality, 4) assessment of reliability, and 5) assessment of criterion and known-groups validity. **Results:** The PROMPT-QOL contained 43 items including nine domains, and their five-point Likert scale functioning worked well. Most items fulfilled the item selection criteria. The PROMPT-QOL took an average administration time of 13.4 ± 5.8 minutes. Only two items had missing data of 0.1% to 0.2%. All domains provided good to excellent test-retest reliability with intraclass correlation coefficients between 0.67 and 0.83. All domains of the PROMPT-QOL yielded high Cronbach's α values between 0.77 and 0.89, greater than an acceptable level of 0.70, except for the Availability and Accessibility domain (0.58). A multiple regression showed that the Medication Effectiveness domain was the strongest predictor of the overall QOL of the PROMPT-QOL, followed by the Therapeutic Relationships, Psychological Impacts, Convenience, and Availability and Accessibility domains (adjusted $R^2 \sim 52\%$). As expected, patients with higher PROMPT-QOL domain scores were associated with being younger, more educated, having a lower number of medicines, patients' perceptions of better disease control, having no adverse drug reactions, and medicine preference. **Conclusions:** The PROMPT-QOL was practical, reliable, and valid for Thai patients.
Keywords: medicine/pharmaceutical/drug therapy, patient-reported outcomes, psychometrics, quality of life, Rasch analysis, Thailand.

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Introduction

Pharmaceutical therapy improves the health of patients suffering from a disease but it also causes undesirable effects, which can negatively affect their post-treatment health-related quality of life (QOL) [1]. Examples of undesirable effects include misunderstanding of medication use, expectation of effectiveness, fear of adverse drug reactions (ADRs), and inconvenience. Cipolle et al. [2] call these drug therapy problems as drug-related needs (DRNs) including indication, effectiveness, safety, and convenience [2]. When patients do not understand or lack information about their drug therapy, they are experiencing DRNs about indication. If they expect, worry, and feel inconvenient about their medication treatment, they are showing their DRNs in terms of effectiveness, safety, and convenience, respectively. Because no well-standardized health-related

QOL tool has been available for identifying DRNs and the impact of medicine use, our research team has developed a new generic questionnaire called the Patient-Reported Outcomes Measure of Pharmaceutical Therapy for Quality of Life (PROMPT-QOL). It was originally developed in Thai and created on the basis of the concept of patient-centered pharmaceutical care [2]. We expect this instrument to be used as a screening tool for identifying DRNs and as a humanistic outcome measure of pharmaceutical care interventions in the future.

The PROMPT-QOL comprised 43 items including 10 domains. The conceptual development of each domain, item generation, content validity, and preliminary psychometric properties of the PROMPT-QOL have been reported elsewhere [3]. On the basis of patient interviews and expert reviews, the PROMPT-QOL was considered important, useful, comprehensive, and comprehensible.

Moreover, the preliminary psychometric properties of the PROMPT-QOL were tested using a Rasch analysis, which revealed that eight items were misfit (infit and outfit mean squares were less than 0.7 or more than 1.3) and two domains (Medicine Information and Psychological Impacts of Medication Use) were reliable for both personal and item aspects. Nevertheless, these results were based on only 60 patients from a hospital. This study therefore aimed to evaluate the psychometric properties of the PROMPT-QOL using both classical test theory (CTT) and Rasch analysis in a large sample size.

Two psychometric tests are commonly used, CTT and item response theory (IRT). Two main limitations of the CTT are that the statistical test is sample- and score-dependent [4]. In other words, the item performance can be misled by the sample, and the questions being tested or the estimates of the person's response can be influenced by the items. The independence in the Rasch measurement model, an IRT family model, can be achieved when the raw scores are log-transformed into a logit scale, allowing the transformation of a categorical scale to an interval scale [5]. In addition, because individual items and persons are examined systematically and simultaneously, this could lead to more precise estimates of the outcomes being measured with fewer samples [6]. Compared with the CTT and other types of IRT, the Rasch model is more restrictive because only those observations fit to model requirements are allowed for the analysis [6]. Therefore, CTT helps to fulfill the need to capture the whole picture of the psychometric properties of the PROMPT-QOL.

Methods

Patients were recruited from three university hospitals in Bangkok, Thailand, between July 2014 and March 2015. They included King Chulalongkorn Memorial Hospital (N = 400), Ramathibodi Hospital (N = 400), and Phramongkutklao Hospital (N = 356). Outpatients aged 18 years or older and who were continuously taking any medicines for at least 3 months to treat their diseases were included in the study. Patients with cognitive impairment or with communicative or psychiatric problems such as schizophrenia were excluded. To identify patients with cognitive or communicative problems, they were retrospectively probed about four to five random questions of the PROMPT-QOL if they understood them. While the patients waited to see their physicians, they completed the questionnaires through self-administration (N = 860) or the questionnaires were read to them if required without any explanation of the items' meanings (N = 296). Written informed consent was obtained from all the patients. The study was approved by the ethical committees of all the three hospitals.

The PROMPT-QOL was a paper-based instrument. It had 43 items including 10 domains: General Attitude toward Medication Use (one item), Medicine Information (seven items), Disease Information (two items), Medicine Effectiveness (three items), Impacts of Medicines and Side Effects (eight items), Psychological Impacts of Medication Use (nine items), Convenience (three items), Availability and Accessibility (four items), Therapeutic Relationship with Health Care Providers (three items), and Overall QOL (three items). The definitions of the domains are given in Supplemental Materials found at http://dx.doi.org/10.1016/j.vhri.2017.02.003. Each item had a five-point Likert scale except the General Attitude toward Medication Use domain, which used four choices for asking patients about their treatment preferences (medicines, alternative medicines, both, and others). The domain scores of the PROMPT-QOL ranged from 0 to 100, with a higher score indicating better QOL. They were calculated using the following formula: Domain score = 100 × (observed score − minimum domain score)/(maximum domain score − minimum

domain score). For example, if a patient is rated level 4 for all three items of the Overall QOL domain, his or her score for this domain would be 75, calculated as 100 × (12 − 3)/(15 − 3).

The psychometric properties of the PROMPT-QOL were assessed in five steps: 1) assessment of dimensional structure, 2) item selection, 3) assessment of practicality, 4) assessment of reliability, and 5) assessment of criterion and known-groups validity [7].

An exploratory factor analysis using the principal-component analysis for extraction and the varimax method for rotation was conducted to determine the number of factors using eigenvalues more than 1.0. A confirmatory factor analysis (CFA) was performed using a maximum-likelihood method to confirm the final model of the PROMPT-QOL. Assessments of good fit were the following: 1) relative chi-square (χ^2/df) was 1.0 to 2.0; 2) a root mean square error of approximation was less than 0.05; 3) a comparative fit index was higher than 0.95; and 4) an adjusted goodness-of-fit index was higher than 0.95 [8,9].

Item selection was undertaken using both CTT and Rasch analysis as follows.

For the CTT approach, the item selection was based on 1) missing data being less than 5%, 2) floor/ceiling effects less than 80% (response choices with high endorsement rates at the bottom/top ends of the scale, respectively), 3) no item redundancy (inter-item correlation < 0.75), 4) corrected item-total correlation more than 0.25, 5) factor loadings more than 0.40 on a single factor or no loadings more than 0.40 on more than one factor, and 6) item importance [7,10].

For the Rasch analysis, infit and outfit mean squares are considered as satisfactory model-data fit when infit and outfit mean squares are 1.0; a value less than 0.5 or greater than 1.5 is considered misfit [11]. Moreover, the Rasch analyses of the five-point Likert scale of each domain of the PROMPT-QOL were conducted. The Likert scale functioning was examined by analyzing category frequencies, mean measures, thresholds, and category fit statistics [12]. Each category should have at least 10 observations. Mean measures and thresholds should increase monotonically. Outfit mean squares should be less than 2.0.

Practicality was evaluated by administration times and the percentage of missing data. For reliability assessment, only self-administered patients were asked to answer the PROMPT-QOL again in the next 1 to 2 weeks for test-retest reliability at home and return the questionnaire via mail. They were also asked whether they still took the same impact medicine and to compare their perceptions about overall QOL of drug therapy between the past and the present assessments. If the patients reported no change in their perceptions, they were used for the test-retest. Of all 1156 patients, 471 patients were eligible for evaluating the test-retest reliability. Internal consistency and test-retest reliability were assessed by using Cronbach's α and intraclass correlation coefficients (ICCs), respectively. Acceptable Cronbach's α values were 0.70 or higher [13], and ICCs less than 0.40, between 0.40 and 0.75, and 0.75 or higher indicated poor, fair to good, and excellent agreement, respectively [14]. ICCs were calculated using one-way random and single-measure methods.

For criterion validity, because there was no criterion standard of medication therapy–related QOL, a multiple regression model using the stepwise method was applied to assess the relationships between the PROMPT-QOL domains and its own Overall QOL domain.

For known-groups validity, because the distributions of all PROMPT-QOL domains were normal, independent t tests and analysis of variance were performed to assess the differences between PROMPT-QOL domain scores and patient characteristics. It was hypothesized that patients with higher scores of PROMPT-QOL domains were associated with being younger, male, more educated, having lower number of medicines, having patients'