

Development and Validation of the Peptic Ulcer Scale under the System of Quality of Life Instruments for Chronic Diseases based on Classical Test Theory and Generalizability Theory

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Research article

Keywords: Quality of life, Peptic ulcer, Standardized response mean, Psychometric properties, Generalizability Theory

Posted Date: October 21st, 2020

DOI: <https://doi.org/10.21203/rs.3.rs-61801/v2>

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Version of Record: A version of this preprint was published on December 14th, 2020. See the published version at <https://doi.org/10.1186/s12876-020-01562-y>.

Abstract

Background: Quality of life (QOL) for patients with Peptic ulcer disease (PUD) is of interest worldwide and disease-specific instruments are needed for clinical research and practice. This paper focus on the development and validation of the PUD scale under the system of Quality of Life Instruments for Chronic Diseases (QLICD-PU) by the modular approach and both classical test theory and Generalizability Theory.

Methods: The QLICD-PU is developed based on programmatic decision-making procedures, including multiple nominal and focus group discussions, in-depth interviews, and quantitative statistical procedures. Based on the data of 153 PUD inpatients, correlation analysis, factor analysis, t-test, and Generalizability Theory analysis (including generalizability study and decision study, ie. G-study and D-study) were used to assess the validity, reliability, and responsiveness of the scale.

Results: When the popular scale health survey short form (SF-36) was used as the standard, correlation and factor analysis confirmed good construct validity and criterion-related validity of QLICD-PU. Except for the social domain (0.62), the internal consistency α of all domains is higher than 0.70. The overall score and the test-retest reliability coefficients (Pearson r and intra-class correlation ICC) in all domains are higher than 0.80 (0.77 in the social domain). After treatments, the overall score and scores of all domains have statistically significant changes ($P < 0.01$), except for social impact and sexual function scores. The SRM of domain-level scores ranges from 0.34 to 1.03. The G coefficient and reliability index (Φ coefficient) further confirm the reliability of the scale through more accurate variance components and decision-making information about changes in the number of items.

Conclusions: The QLICD-PU can be used as a useful measurement to assess the quality of life of PUD patients with good psychometric characteristics and multiple advantages.

Backgrounds

Peptic ulcer disease (PUD) is a frequently occurring and common disease in the world and is usually recurrent [1-5]. Its annual incidence rate is 1.1-3.3%, the prevalence is 1.7-4.7% and about 10% of the people are suffered from this disease during their lifetime in the United States [1-2]. In Europe, about 10% of the population experience PUD in their lifetime [4-5]. Patients with PUD may have various gastrointestinal symptoms including abdominal pain, vomiting, and even upper gastrointestinal bleeding and perforation which is related to high mortality and high morbidity [6-7]. Considering the disease can result in pain, bleeding and GI discomforts like nausea, anorexia and some limitations to social and mental health, it is particularly important to evaluate their overall impact from the patient's health-related quality of life (HRQOL) [8,9]. Several studies showed that patients with PUD had significantly lower health-related quality of life than the general population and the improvement in HRQOL in patients with PUD plays an important role in the treatment of the disease [9,10]. It is hoped that the use of appropriate tools can improve the understanding of the treatment and service needs of PUD patients.

There are many HRQOL instruments which can be divided into general measures and measures against diseases. The application of general and specific quality of life measures is different. General measures must be taken to compare the results of different populations and interventions. Specific measures are more sensitive to detect and quantify subtle changes that are important to clinicians or patients [11]. For the last few decades, although the measurement of general QOL has been improved using the popular scale health survey short form (SF-36), PGWB (Psychological General Well-Being) index, etc., clinicians and researchers still need to determine the clinical significance of any measure of patients' response to treatment. Therefore, several HRQOL measures against PU have been developed for diseases, such as QPD (quality of life in peptic disease)[12], QLDUP (Quality of Life in Duodenal Ulcer Patients) [13]. Besides, the QOLRAD (Quality Of Life in Reflux and Dyspepsia) [14,15], the FDDQL (Functional Digestive Disorder Quality of Life Questionnaire) [16] and the GSRS (Gastrointestinal Symptom Rating Scale) [17] can also be used for patients with PUD. Among them, the QLDUP has 54 items with 15 dimensions and was developed by combining the SF-36, PGWB index, and 13 disease specific items derived from patient and clinician interviews. The QOLRAD is a 25 item questionnaire with each item scored on a seven point Likert scale, and has five subscores.

However, these instruments are not developed based on the popular modular approach-a general/core module plus the specific modules [18,19]. Since diseases within the same disease class such as digestive diseases share many characteristics such as symptoms and side effects in common, an approach widely adopted in recent years to develop QOL instruments for diseases is to combine a general module for the entire class of diseases with the specific module for each individual disease. This approach can greatly reduce the time and effort of developing new instruments. For example, the quality of life questionnaires (QLQs) from EORTC (European Organization for Research and Treatment of Cancer)and the Functional Assessment of Cancer Therapy (FACTs) have been developed based on this modular principle [18,19].

To the best of our knowledge, no instrument for PUD has been developed based on the modular approach, let alone a combination of classic test theory (CTT) and generalizability theory (GT).To fill the gaps in QOL research and meet the needs of such research and clinical studies, we developed a set of Quality of Life Instruments for Chronic Diseases (QLICD) through a modular approach [20-23]. The system includes a general module (QLICD-GM) which can be used for all types of chronic diseases, as well as specific modules only for related diseases [20-23]. For example, the coronary heart disease instrument (QLICD-CHD) is constructed by combining QLICD-GM with the specific module for coronary heart disease [21]. At present, the QLICD (V1.0) includes a 30-items general module QLICD-GM (3 domains and 10 facets) and 9 specific modules with the numbers of items ranging from 14 to 21, and thus forming 9 specific scales of coronary heart disease (QLICD-CHD)[21], hypertension (QLICD-HY)[22], irritable bowel syndrome (QLICD-IBS) [23], peptic ulcer disease (QLICD-PU) etc.

In the current research, we aimed to develop and validate the QLICD-PU instrument.

Methods

Development of the QLICD-PU

The QLICD-PU consists of a general module QLICD-GM and a module dedicated to PUD. The development process of QLICD-GM has been described in another paper [20]. Here, we briefly summarize the development steps and results. The programmed develop procedures which include focus group discussions, in-depth interviews, pre-testing, and four quantitative statistical analyses were used in the QLICD-GM. Finally, the QLICD-GM has 30 items which included 3 domains and 10 facets. Based on the data of 620 patients with seven kinds of chronic diseases such as coronary heart disease and hypertension, the QLICD-GM has good psychometrics (reliability, validity, responsiveness) [20].

For a specific module, 29 items reflecting symptoms were selected to constitute the initial item pool. These items focus on the unique side effects and mental health of PUD. We selected these items from literature reviews and nominal / focus group discussions. Focus groups evaluate the importance of each item by ranking each item independently and then discussing the 9 lowest ranked items that are excluded. The remaining 20 items constitute a preliminary questionnaire for conducting the pilot test and also Interviews with 29 PUD patients and 14 clinicians and researchers with extensive experience. We focus on patient opinion, which is most important for assessing the acceptability of interventions and related compliance. Based on the pilot data, the items were re-screened using a development process similar to the generic module (statistical procedure and focus group discussion). The final specific module consists of 14 items, coded PU1-PU14 (see table 1 in detail), classified into 6 facets.

Validation of the QLICD-PU

Data Collection and Scoring

In this study, we enrolled participants with PUD at any stage who were: (1) be able to provide written informed consent; (2) be able to read and write words with assistance. There were no protocol requirements regarding specific clinical treatment of patients. Physicians could treat the patients according to what they deemed clinically appropriate.

The survey was carried out at the First Affiliated Hospital of Kunming Medical University after approved by the ethics committee of Kunming Medical University. Researchers including doctors and medical graduate students explained the purpose of the study and obtained informed consent before the test. Each interviewee was required to answer the questionnaire upon admission. To assess the reliability of the test-retest, a subsample is randomly selected for the second assessment on the second day of hospitalization. All patients available at the scheduled third evaluation time point have completed discharge measures to assess the responsiveness of the questionnaire. Besides, the Chinese version of SF-36 [24] was also used to provide data for assessing the criterion-related validity, convergent and discriminant validity of the QLICD-PU because of the lack of an agreed-upon gold standard for assessing QOL of PUD. Baseline socio-demographic characteristics were recorded from hospital medical records, including age, gender, education level, marital status, clinical history, and treatment. Each investigator checked the answers immediately to ensure their integrity.

Since each item uses the five-point Likert format (not at all, a little bit, somewhat, quite a bit, and very much), positively stated items will be scored directly from 1 to 5, while negatively stated items will receive the opposite score. The domain/facet and overall scores are obtained by adding related item scores, all of which are linearly converted to standardized scores on a scale of 0-100. The higher the score of QLICD-PU means the better quality of life for both raw and standardized scores.

Psychometric Analysis

Then the validity, reliability, and responsiveness of QLICD-PU were evaluated. In this study, the construct validity is evaluated by the Pearson correlation coefficient (r) between the items and the domains and also by factor analysis. Assess the criterion-related validity by correlating the corresponding domains of QLICD-PU and SF-36. Multi-trait scaling analysis [25] is used to test the convergence validity and discriminant validity. There are two validity criteria: (1) When the item-domain correlation is 0.40 or higher, it supports convergence validity; (2) discriminant validity is revealed when item-domain correlation is higher than that with other domains. In terms of reliability, for each domain/facet and the overall scale, the internal consistency is assessed using the first measurement data (at admission) by Cronbach's alpha coefficient. Evaluation of test-retest reliability was by Pearson correlation coefficient and intra-class correlation (ICC) [26-27] between the first and second assessments. The responsiveness (sensitivity to detect change) was assessed by using a paired t-test to compare the average score change between the two assessments before and after treatments and also the effect size, standardized response mean (SRM) [28-29].

Generalizability Theory Analysis

In addition to the classical test theory analysis, we also applied the Generalizability Theory (GT) in this research to study the reliability of the QLICD-PU score. GT is a modern test theory developed based on the combination of classical test theory and analysis of variance. It is proposed as a method to improve measurement program design in an attempt to obtain reliable data [30-33]. To control the measurement errors, GT introduces independent variables or factors that interfere with test scores into measurement models, such as differences between research objects, item difficulty, scoring criteria, and the interaction between these factors. An analysis of variance was then used to assess the impact of these variables or factors on test scores, using the variance component as an index. GT includes generalizability study (G-study) and decision study (D-study). G study quantified the amount of variance related to the different facets (factors) to be examined. D study provides information about which protocol is best for a particular measurement by generating a generalizability (G) coefficient, which can be interpreted as a reliability factor for all facets of the current study.

In our research, both G study and D study are completed in one measurement model to estimate the variance components and dependability coefficients in one-facet crossed design (person-by-item design, ie. $p \times i$ design). We define the patient's quality of life as the measurement target and the item as a facet of measurement error. For G-Study, we defined an acceptable observation range composed of measurement objects and measurement errors and estimated variance components. For D-study, we

define the allowable summary based on the measurement object and the measurement facet that the researchers are willing to summarize to express the measurement conditions. At the same time, the generalized coefficients of each facet and the variance components of the reliability indicators and their interactions are calculated.

Results

Socio-demographic characteristics of the sample

153 PUD patients range in age from 16 to 79, with a mean age of 45.2 ± 14.8 . 110 cases (71.9%) were male, and 134 (87.6%) were of Han ethnicity. 27 cases (17.6%) finished primary school, while 85 (55.5%) completed high school, and 40 (26.2%) had a university or graduate degree. In terms of occupation, workers accounted for 38.6% (59 cases), farmer 15.0% (23), cadre 12.4% (19), teacher 9.2% (14), and others 24.8% (38). For perceived Income, poor accounted for 30.7% (49 cases), fair 58.8% (90), and high 9.2% (14).

Construct validity

The construct validity was evaluated by item-domain Pearson's correlation coefficient r and by factor analysis. A correlation analysis from the data measured at the time of admission shows that there is a strong correlation between the items and their domain (most above 0.40). However, the relationship between the item and other domains is weak (see Table 1 in details). For example, the correlation coefficient between PHD and PH1-PH8 is between 0.49 and 0.76 (the first column in bold) are higher than those between PHD and other items. Similarly, correlation coefficients between PSD and items of PS1-PS11 ranging from 0.44 to 0.72 (the second column in bold) are higher than the value between PSD and other items. Factor analysis was performed on the general module and the specific module respectively. Extraction standard was set as criteria of eigenvalues >1 , there were 8 principal components extracted from 30 items of the general module (QLICD-GM), accounting for 63.88% of the cumulative variance. By using the Varimax rotation method, it can be seen that the 8 principal components reflected 8 different facets under three domains of the general module with the first, fourth and fifth principals components mainly representing the psychological domain with higher loadings on PS1-PS11; the second and seventh principal components largely reflecting the physical domain with higher loadings on PH1-PH8; the third, sixth and eighth principal components generally depicting the social domain with higher loadings on S01-S011. Similarly, the principal component factor analysis extracted 6 principal components from the 14 items of the specific module with the cumulative variance of 65.88%, reflecting 6 facets.

Criterion-related validity

The correlation coefficients between the QLICD-PU and SF-36 domain scores were listed in Table 2, indicating that the correlation between the same and similar domains (bold in the table) is usually higher than different and dissimilar domains. For example, the coefficient between the physical domain of

QLICD-PU and the physical function of SF-36 is 0.67, which is higher than any other coefficient in this row. Similarly, the coefficient between the psychological domain of QLICD-PU and the mental health of SF-36 is 0.51, higher than any other coefficient in the row

Reliability

As shown in Table 3, the Cronbach's α for these four domains were higher than 0.70 except for SOD (0.62), while they were ranging from 0.35 to 0.81 at facets level.

In the second evaluation (two-day follow-up), data from 63 patients were used for test-retest reliability analysis. The test-retest correlation coefficients for the 4 domains and the overall were larger than 0.80 except for SOD (0.77), while they were ranging between 0.72-0.94 at facets level. The ICC result calculated according to the definition of absolute consistency is very similar to the Pearson correlation coefficient.

Results from Generalizability Theory

G-Studies were performed to estimate the variance components for four domains of the QLICD-PU (see Table 4), in which 153 patients filled out the quality of life the instrument with 44 items.

As can be seen from Table 4, for the four domains of physical, psychological, social and the specific, the largest source of variation were due to person-by-item interactions ranging from 55.68% to 81.89%, while variances accounted for by person were the second for three domains of physical, psychological and social ranging from 12.20% to 35.92%.

The D-Studies were performed to estimate the Generalizability coefficient (G-coefficient) and index of dependability (Φ coefficient) for four domains of the QLICD-PU for the $p \times i$ current design (physical domain includes 8 items, psychological domain includes 11 items, social domain includes 11 items and specific domain includes 14 items), as well as the alternative designs with varied numbers of items (see Table 5).

Responsiveness

The data from 135 patients who completed the questionnaire after treatments were used to assess responsiveness. The paired t-test and the response index SRM were used to check the average score change of each domain/facet of QLICD-PU before and after treatments. The results are shown in Table 6. It can be seen that except for social impact and sexual function, all domains/facets and overall scale have undergone major changes ($p < 0.01$), with SRM ranging from 0.04 to 1.03 and domain-level SRM from 0.34 to 1.03.

Discussions

The focus of this study was to develop and validate a special QOL instrument QLICD-PU for peptic ulcer disease. We use a method that combines a general module with a specific module for a specific disease to capture common features within the disease category and the differences between specific diseases [18-20]. We adopted a modular approach to systematically and effectively develop new instrument systems for chronic diseases, in which the general module QLICD-GM is used for various chronic diseases, and QLICD-PU is only for a specific scale of PUD. This method uses the same general module and similar structure to unify all QLICD specific disease tools. Compared with existing instruments, QLICD-PU has several advantages [20-23]. First, it can compare the QOL of various diseases through a general module, and can also capture symptoms and side effects through a specific module. We can use QLICD-GM to capture general QOL in patients with different diseases. We can also employ QLICD-PU and QLICD-CG to capture differences in QOL in PUD and chronic gastritis patients. Secondly, it consists of a moderate number of items with a clear hierarchy (item → facet → domain → overall), so the mean can be calculated to detect detailed changes, not only at the domain level (4 domains) but also at the facet level (16 facets). Users can choose one or two levels for research at their convenience. Third, the most important value of QLICD-PU is the profound Chinese cultural background behind it. For example, Chinese culture focuses on family relations and pedigree, diet, temperament, and noble spirit, all of which are reflected in QLICD-PU through items that focus on appetite, sleep, energy, and family support.

Practical QOL instruments require excellent psychometric characteristics, including validity, reliability, and responsiveness. Validity is the degree to which the tool can capture what it claims to measure. Follow WHO's definition of quality of life [34] and systematic development procedures, we developed QLICD-PU for PUD patients through focus group discussions, in-depth interviews, and pre-tests to effectively reduce the number of items. The final version effectively reduce the number of items in the final version to 30 from an initial 73 item bank for the general module [20], and it has been reduced to 14 items from the first 29 items of specific modules. This process helps us achieve good content validity and conceptual structure of this instrument. Correlation and factor analysis are used to confirm the construct validity. Correlation analysis shows that the relationship between items and their domains/facets is strong, but the relationship between items and other domains/facets is weak. Factor analysis shows that the components extracted from the data are consistent with the theoretical structural framework of the instrument. These results confirm evidence supporting the good construct validity. The correlation coefficients between the QLICD-PU and SF-36 domain scores demonstrated that the criterion-related validity and construct validity (the convergent and divergent validity) are both high.

Reliability refers to the repeatability or consistency of item ratings in different assessments. In this study, internal consistency reliability (Cronbach's α), test-retest reliability (Pearson r) and ICC were applied. Our results show that the internal consistency coefficient and the overall score of the QLICD-PU domain are both greater than 0.70 except for the social function domain (0.62). The test-retest reliability coefficient of the overall score is 0.89, while the test-retest reliability coefficients of domains are greater than 0.80 (except for social function domain) (0.77). Taking into account that the internal consistency coefficient is greater than 0.70 and the test-retest reliability coefficient is greater than 0.80 is considered satisfactory, these results indicate that the instrument has good reliability overall.

Responsiveness (sensitivity to detect changes) is the most important desirable characteristic of the QOL scale in clinical applications. There are two types of assessment methods: internal and external [28, 29]. In this study, we used a paired t-test to focus on internal responses to compare the average response before and after treatment. We used SRM as a responsiveness indicator, with 0.20, 0.50, and 0.80 representing small, moderate, and large responsiveness [28,29]. The QOL scores had significant changes after treatments for all domains and the overall score ($P < 0.001$) with SRM being greater 0.70 except for the social function domain (0.34), suggesting QLICD-PU has good responsiveness.

In addition to classical test theory analysis, this study also applies generalization theory. The reliability indicators are usually lower than the G factor because in addition to the interaction of the G factor, they also consider the main error effects. This study not only introduced the G coefficient and Φ but also introduced their changes when the item changed. For the physical and psychological fields, we estimate that the currently designed G coefficients are 0.787 and 0.830 and the credibility index is 0.755 and 0.815, respectively. It can be considered that it meets the 0.70 standards. For the social domain, the current design G-factor is estimated to be 0.622, and the reliability index is 0.605, which is lower than the acceptable 0.70. Therefore, the items of this domain need to be improved. For an alternative design with 17 items, the G coefficient is estimated to be 0.717 and the reliability index is 0.703, which will satisfy acceptable reliability. For the specific domain, the G coefficient of the current design is estimated to be 0.626, and the reliability index is 0.580, which is also lower than the acceptable 0.70. Similarly, the G-coefficient estimated to be 0.742 and the index of dependability 0.703 when an alternative design with 24 items. Therefore, these analyses suggest that the number of items of the social domain needs to be increased from 11 to 17, and the specific domain from 11 to 24 to reach acceptable dependability. However, it may not be practical to increase the length of the test in practice, as reliability is reduced if the subject is required to complete too many items at the same time. Researchers or instrument users can decide to add items or tolerate reasonable low reliability.

Conclusions

In conclusion, QLICD-PU can be used as a useful tool for assessing the quality of life of patients with PUD, with good psychometric characteristics and many advantages. The analysis from Generalizability theory not only confirmed the reliability of the scale as a whole, but it also provides more information than CTT. However, the number of social and the specific items should be increased to increase reliability. Besides, the quality of items in these 2 domains should also be addressed.

List Of Abbreviations

CTT: Classical Test Theory;

D-study: decision study;

FDDQL: Functional Digestive Disorder Quality of Life Questionnaire;

G-study: generalizability study; GSRS: Gastrointestinal Symptom Rating Scale; GT: Generalizability theory;

HRQOL: Health-Related Quality Of Life;

ICC :Intra-Class Correlation;

PGWB: Psychological General Well-Being; PUD :Peptic ulcer disease;

QLDUP: Quality of Life in Duodenal Ulcer Patients;

QLICD: Quality of Life Instruments for Chronic Diseases; QOL: Quality of life;

QOLRAD :Quality Of Life in Reflux and Dyspepsia ; QPD: quality of life in peptic disease;

SRM: Standardized Response Mean;

Declarations

Ethics approval and consent to participate

The study protocol and the informed consent form were approved by the IRB (institutional review board) of Kunming Medical University (30860248, Kunming Medical University, 01/17/2009).

Consent to publish

The authors understand and agree to publish.

Availability of data and materials

The data can be available by request.

Competing interests

The authors declare that they have no competing interests.

Funding

The paper is supported by the National Natural Science Foundation of China (71373058, 30860248), Science and Technological Planning Program of Guangdong Province(2013B021800074). The funding bodies provided funds to support project development. The grant recipient (Chonghua Wan) designed the study, performed the data collection and data analyses, and extensively revised the manuscript.

Authors' contributions

WCH and CY designed the study. GL, ZQQ performed the data collection and WCH,QP performed data analyses, and all authors contributed to interpreting the data. WCH SXY and ZQQ wrote the first draft, which was critically revised by all others. All authors have read and approved the final manuscript.

Acknowledgments

In carrying out this research item, we have received substantial assistance from Liping Duan, Hongying Li and Wu Li at the first affiliated hospital of Kunming Medical University, Bin Wu and Fuzhen Liu at the affiliated hospital of Guangdong Medical University, and Susan Messing at University of Rochester, NY, USA. We sincerely acknowledge all the support.

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Tables

Due to technical limitations, tables 1-6 are only available as a download in the supplemental files section.

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