

QUALITY OF LIFE OF PATIENTS WITH PEPTIC ULCERS: DEVELOPMENT AND VALIDATION OF INSTRUMENT

Hoang Ngoc Yen¹, Tran Vinh Quang¹, Dao Duc Tien², Vo Quang Trung^{1*}

¹Pham Ngoc Thach University of Medicine - No.2, Duong Quang Trung, Ward 12, District 10, Ho Chi Minh City, Vietnam

²Military Hospital 175 - 786 Nguyen Kiem, 3 Ward, Go Vap, Ho Chi Minh City, Vietnam

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ABSTRACT

Introduction: Peptic ulcer disease is a prevalent and frequently recurring ailment, characterized by evolving etiological factors and risk elements that present difficulties in its management. Consequently, the quality of life of those suffering from peptic ulcers might be substantially influenced, thereby raising concerns.

Objective: To develop a Vietnamese version of the Quality-of-Life Instruments for Chronic Diseases - Peptic Ulcer Scale (QLICD-PU), a specialized tool designed to assess the QLICD-PU' patients.

Materials and methods: In the month of April 2023, a cross-sectional study was undertaken. The data were obtained by conducting direct interviews with patients diagnosed with peptic ulcer disease (PUD) who were undergoing therapy. The interviews were conducted using the QLICD-PU tool.

Results: The study involved a sample size of 146 patients. The examination of the reliability scale resulted in Cronbach's alpha coefficient that above 0.6. The findings of the Exploratory Factor Analysis (EFA) indicated that all items demonstrated factor loadings of at least 0.3. In the context of Confirmatory Factor Analysis (CFA), the majority of the scale's components demonstrated satisfactory model fit indices, with the exception of the GFI and NFI indices pertaining to the general Quality of Life (QoL) and PUD-specific sections.

Conclusion: The validity and reliability of the Vietnamese adaptation of the QLICD-PU Quality of Life measure have been demonstrated, rendering it a valuable instrument for evaluating the QLICD-PU in Vietnam.

Keywords: EFA, quality of life, QLICD-PU, peptic ulcer, reliability.

*Corresponding author

Email address: trungvq@pnt.edu.vn

Phone number: (+84) 988 422 654

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1. INTRODUCTION

Peptic ulcer disease is one of the most common digestive disorders, found in all ages, occur both acutely and chronically, often recur and are known as one of the most common cause of death in the world [1]. In Vietnam, up to 26% of the population suffers from peptic ulcer disease, the acquired risk in men is 4 times higher than in women and tends to increase with age [2].

Around the world, a number of studies have applied QoL indexes to evaluate the effectiveness of treatment [3, 4]. Because peptic ulcer disease poses many challenges, standardized QoL measurement tools are essential. To solve this problem, in 2020, Chonghua Wan and his colleagues developed the first version of the Quality of Life Instruments for Chronic Diseases-Peptic Ulcer Scale (Quality of Life Instruments for Chronic Diseases-Peptic Ulcer Scale, QLICD-PU) for patients with peptic ulcers, version 1.0) meets the general and specific QoL assessment criteria based on the integrated design between the general module (QLICD-GM), can be used for all types of chronic diseases or only for peptic ulcer disease. The QLICD-PU 1.0 instrument has been determined for accuracy, reliability and effectiveness on 153 people with peptic ulcers in China [5]. The questionnaire has the following advantages: it is possible to compare the QoL of different chronic diseases through the common module, and at the same time it can capture the symptoms and unwanted effects of the disease through the specialized module. In addition, the questionnaire includes many levels of assessment (general QoL, sections, domains, aspects) with the same standard scale from 0 to 100, allowing to detect and compare small changes in patients' QoL.

In Vietnam, until 2023, only the 36-Item Short Form Health Survey (SF-36) will be applied to evaluate QoL in people with peptic ulcers [2]. To date, there have been no studies in Vietnam using specialized tools on this patient population. Therefore, this study was conducted to develop a Vietnamese version of the QLICD-PU instrument based on data collected from peptic ulcer patients at Military Hospital 175 in 2023.

2. METHODS

2.1. Time and location of research

Location: Military Hospital 175, Ho Chi Minh city.

Time: From 3/2023 to 4/2023.

2.2. Research design

Cross-sectional, prospective research, convenience sampling.

2.3. Research subjects

Outpatients diagnosed peptic ulcer are being treated at the Gastroenterology Department of Military Hospital 175.

Selection criteria: Patients with diagnosis codes K25, K26, K27 according to ICD-10 code (International Classification of Diseases, 10th Revision); endoscopic results of peptic ulcer; from 16 years old and above [5, 6].

Exclusion criteria: Patients with mental illness, behavioral disorders or mental dementia; patients with insufficient data for research purposes; patients were re-examined during the study period.

2.4. Research instrument

Translating the QLICD-PU questionnaire and adapting it to social culture

The English version of the QLICD-PU questionnaire was translated into Vietnamese by two medical researchers. The translation of each item will be discussed to ensure that the questionnaire is complete, concise and easy to understand, as well as suitable for short interviews. Next, the translated version will be compared to the original language version by experts to reach linguistic consensus. After that stage, the questionnaire was asked for opinions from 5 peptic ulcer patients about the understandability of each question. Responses will be reviewed and evaluated. Finally, a meeting was held including 7 members, the translations were compared, contrasted and commented on by the research team to resolve conflicts and shortcomings in the translation process and ensure clarity, consistency, appropriateness and readability, then acquired consensus before evaluation by a pilot survey.



Evaluate the validity and reliability of the QLICD-PU questionnaire

The validity of the scale (construct validity) between questions and domains is assessed by Pearson correlation coefficient (Pearson correlation coefficient - r), exploratory factor analysis (EFA) and Confirmatory Factor Analysis (CFA). Reliability was assessed based on calculating Cronbach’s alpha coefficient (α) for all questions in the questionnaire and each field of physical, psychological, social and specialized fields for patients with peptic ulcers, Cronbach’s alpha value is in the range of $0.6 \leq \alpha \leq 0.7$, which is considered acceptable for surveys, and $\alpha \geq 0.7$, the questionnaire has good reliability. The Kaiser-Meyer-Olkin (KMO) index was also used to consider the appropriateness of EFA factor analysis in the questionnaire. If $0.5 \leq KMO \leq 1$, factor analyzes are appropriate.

2.5. Data analysis

The QLICD-PU questionnaire will be converted into raw scores, standard scores and total scores, and the results will be expressed using descriptive statistics. The direct score were assigned value from 1 to 5 with questions asked positively, and questions asked

negatively were assigned a reverse score from 5 to 1. Raw score (RS) for each sub-dimension equals the total score of related questions from 0 to 100.

Standard score were calculated using the following formula:

$$SS=(RS-Min) \times 100/R$$

In which: SS standardized score; RS: raw score; Min: minimum; R (range of scores): highest score - lowest score. Scores are linearly converted to standard scores on a scale from 0 to 100. Higher QLICD-PU scores mean better QoL.

2.6. Research ethics

This study was approved and consented by participants and the Research Ethics Council at Military Hospital 175, Ho Chi Minh City (Decision No. 912/GCN-HDĐĐ on approval of ethical issues of biomedical research dated March 24, 2023).

3. RESULTS

3.1. Characteristics of participants in research

Table 3.1. Characteristics of study participants (n=146)

Variable	n	%	Variable	n	%
Gender			Time of disease (year)		
Male	104	71,2	< 1	66	45,2
Female	42	28,8	≥ 1	80	54,8
Age			Family History		
Mean (Standard Deviation)	50,70 (17,2)		Yes	40	27,4
Min – Max	16 - 84		No	106	72,6
Age group (Age)			History of hospitalization due to peptic ulcers		
16 - 24	20	13,7	Yes	29	19,9
25 - 65	92	63,0	No	117	80,1
≥ 65	34	23,3	Infected <i>Helicobacter pylori</i>		
Living place			Yes	55	37,7
Urban	114	78,1	No	91	62,3
Rural	32	21,9	Other chronic disease		

Variable	n	%	Variable	n	%
Education level			Yes	76	52,1
Below High school	103	70,5	No	70	47,9
High school and above	43	29,5	Number of comorbidities		
Marital status			1	49	64,4
Single/ Widow/ Divorce	31	21,2	≥ 2	27	35,6
Married/ Sharing room	115	78,8	Smoke		
Occupation			Yes	40	27,4
Manual work	60	41,1	No	106	72,6
Intellectual work	27	18,5	Level of smoking		
Student	12	8,2	No	105	71,9
Homemaker/Retire/ Unemployment	45	30,8	Hardly	7	4,8
Others	2	1,4	Sometimes	18	12,3
Income			Often	16	11,0
Sufficient and have saving money	52	35,6	Exercise		
Sufficient	64	43,8	Yes	39	26,7
Insufficient	8	5,5	No	107	73,3
No income/depend	22	15,1	Alcohol		
Diagnosis			Yes	18	12,3
Gastric ulcer	71	48,6	No	128	87,7
Duodenal ulcer	40	27,4			
Gastric-duodenal ulcer	35	24,0			

3.2. Assessing the reliability of the Vietnamese version of the QLICD-PU instrument

The QLICD-PU instrument is divided into two parts: General module (GM) and Peptic Ulcer (PU). The GM part of the QLICD-PU questionnaire includes three domains, namely: PHD, PSD and SOD. These areas

revolve around 6 aspects, through 21 questions used to exploit data about patients' chronic diseases. The PU section of the QLICD-PU questionnaire covers only specialized fields. The specialized field analyzes 3 aspects, using 13 questions only to exploit data about gastric and duodenal ulcer disease of patients participating in the study.



Table 3.2. Results of assessing the reliability of the Vietnamese version of the QLICD-PU instrument

Code	Question/Domain	Cronbach's alpha value (α)
GM	General Module	0,860
- PHD	physical domain	0,684
- PSD	psychological domain	0,865
- SOD	social domain	0,661
PU	Peptic ulcer	0,805
QLICD-PU	Instrument	0,896

When evaluating each section, Cronbach's Alpha coefficient reached >0.7, reflecting the high reliability of the questionnaire ($\alpha=0.896$).

3.3. Assessing the convergent and discriminant validity of the Vietnamese version of the QLICD-PU instrument

Table 3.3. Appropriateness of factor analysis

General Module	KMO coefficient		0,810
	Bartlett test	Chi Square χ^2	1198,197
		df	210
		p	<0,001
Peptic Ulcer	KMO coefficient		0,840
	Bartlett test	Chi Square χ^2	668,520
		df	78
		p	0,001*

Table 3.4. Structure of the general part of the Vietnamese version of the QLICD-PU instrument

Code	Factors	Coefficient of loading factor
General Module		
1. Aspect of anxiety - depression		
PS2	Felt mentally miserable	0,751
PS5	Worried about disease	0,532
PS7	Felt nervous and anxious	0,604
PS3	Felt lonely and helpless	0,755
PS4	Felt pessimism and despair	0,795
2. Aspect of social effect		
SO2	Family roles	0,797
SO1	Interfered with work/housework	0,854

Code	Factors	Coefficient of loading factor
SO3	Decreased caring and attention to family	0,439
SO6	Affected participating in leisure activities	0,585
3. Aspect of physical symptoms		
PH3	Have trouble walking bout 1km	0,814
PH4	Have trouble going up and down stairs	0,857
PH5	Need to take medication	0,580
4. Aspect of self conscious		
PS1	Memory and concentration affected	0,831
PS6	Felt fretful or irritable	0,551
PS9	Feel to be a burden to the family	0,419
5. Aspect of social support		
SO4	Good relations with family	0,693
SO5	Help and support from family	0,850
SO10	Support from friends and relatives	0,801
6. Aspect of appetite, sleep and optimism		
PH6	A good appetite	0,835
PH7	Satisfied with your sleep	0,734
SO7	Treat illness positively and optimistically	0,574
Peptic Ulcer		
1. Effect on spirit - life		
PU10	Upset/distress for gastroscopy inspection	0,612
PU11	Vexed for food limit	0,734
PU12	Troubled/limit by dine at fix time	0,713
PU13	Worried about causing severe disease	0,612
PU14	Vexed for often taking stomach medications	0,751
2. Other symptoms		
PU5	Regurgitation	0,757
PU8	Salivate	0,509
PU6	Burps	0,842
PU7	Abdominal distension	0,738
3. Pain in epigastria		
PU1	Have pain (sore) in epigastria	0,832
PU2	Have heartburn in epigastria	0,638
PU3	Have pain/discomfort at night or hungry	0,640
PU4	Pain/uncomfortable relieved after dinner	0,729



Factor Loading $\geq 0,5$ shows observed vary good, minimum value is 0,3.

Table 3.5. The appropriateness of the structure of the Vietnamese version of the QLICD-PU instrument

General Module	χ^2/df	RMSEA	NFI	CFI	GFI
	1,437	0,055	0,798	0,926	0,861
Peptic ulcer	χ^2/df	RMSEA	NFI	CFI	GFI
	1,518	0,063	0,861	0,942	0,910

Note: χ^2 Chi square, RMSEA: Root mean square errors of approximation, CFI: Comparative fix index, GFI: Goodness of fix index.

3.4. Evaluate the correlation between question and domains in QLICD-PU instru

Table 3.6. The correlation between question and domains in QLICD-PU instrument

Code	PHD	PSD	SOD	PUD	Code	PHD	PSD	SOD	PUD
PHD	1,000	0,555	0,354	0,379	PSD	0,555	1,000	0,434	0,622
PH3	0,642	0,384	0,218	0,230	PS1	0,341	0,608	0,267	0,474
PH4	0,762	0,457	0,234	0,258	PS2	0,387	0,774	0,364	0,447
PH6	0,572	0,211	0,208	0,230	PS5	0,493	0,746	0,307	0,416
PH7	0,578	0,289	0,247	0,151	PS6	0,419	0,784	0,312	0,532
PH5	0,641	0,376	0,143	0,286	PS7	0,433	0,843	0,368	0,502
SO7	0,520	0,335	0,293	0,258	PS3	0,322	0,647	0,226	0,401
PUD	0,379	0,622	0,441	1,000	PS4	0,425	0,722	0,334	0,391
PU1	0,265	0,396	0,157	0,619	PS9	0,358	0,612	0,339	0,399
PU2	0,324	0,415	0,261	0,654	SOD	0,354	0,434	1,000	0,441
PU3	0,301	0,414	0,251	0,733	SO2	0,381	0,460	0,658	0,425
PU4	0,141	-0,288	0,040	0,296	SO4	0,128	0,002	0,545	0,007
PU5	0,162	0,317	0,242	0,563	SO5	0,078	0,099	0,580	0,073
PU8	0,293	0,380	0,164	0,586	SO10	0,044	0,181	0,555	0,148
PU6	0,154	0,340	0,357	0,658	SO1	0,178	0,319	0,583	0,316
PU7	0,218	0,387	0,284	0,660	SO3	0,326	0,383	0,569	0,374
PU10	0,209	0,379	0,272	0,566	SO6	0,321	0,349	0,542	0,469
PU11	0,285	0,317	0,280	0,530					
PU12	0,165	0,328	0,301	0,571					
PU13	0,221	0,572	0,227	0,641					
PU14	0,258	0,469	0,396	0,676					

4. DISCUSSIONS

The Vietnamese version of the QLICD-PU quality of life scale shows good validity and reliability. With the Cronbach's Alpha coefficient of the questionnaire and the psychological and specialized domains reaching a good threshold (>0.8), the physical and social domains reaching an acceptable threshold (>0.6). With the KMO coefficients of the general and specialized parts both above 0.8, it shows that the data in the study are suitable for factor analysis. In exploratory factor analysis, after eliminating 10 inappropriate questions, the scale extracted 9 factors explaining 9 aspects in 4 areas. The results of all factors have an eigenvalue level > 1 , accounting for $> 50\%$ of the accumulated variance, proving that EFA factor analysis is appropriate. All questions had a minimum loading factor of 0.3 to be retained. The results showed that the majority of factor loadings reached >0.5 , reflecting that the observed variables also had good statistical significance at good and excellent level. In confirmatory factor analysis CFA, the indices considered to evaluate the model fit of the two parts mostly reach good thresholds except for the GFI and NFI indexes of the general GM and specialized PU parts. Due to the dependence of this index on the number of observed variables and sample size, GFI and NFI values at a minimum value of 0.8 are still accepted. Thus, the questions in the scale are good indicators of the latent factor and the scale demonstrates internal consistency and validity. Finally, the results show that questions belonging to the specified field only show a correlation with the corresponding field, expressed by a series of values, most of which have values greater than the significance threshold of 0.3, showing that validity of the scale.

5. CONCLUSIONS

The Vietnamese version of the quality of life scale QLICD-PU shows good validity and reliability and can be referenced to evaluate the QoL of peptic ulcer patients in Vietnam.

REFERENCES

- [1] Chan FK, W Leung, Peptic-ulcer disease; *The Lancet*, 2002, 360(9337): p. 933-941.
- [2] Huong HTM et al., Quality of life of patients with peptic ulcer in General Hospital of Vinh Phuc province in 2021. *Journal of Medical Research*, 2022, 156(8): p. 301-310.
- [3] Yeomans N et al., Quality of life in chronic NSAID users: a comparison of the effect of omeprazole and misoprostol. *Scandinavian Journal of Rheumatology*, 2001, 30(6): p. 328-334.
- [4] Fujiwara Y et al., Long-term effect of Helicobacter pylori eradication on quality of life, body mass index, and newly developed diseases in Japanese patients with peptic ulcer disease. *Hepato-gastroenterology*, 2002, 49(47): p. 1298-1302.
- [5] Wan C et al., 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. *BMC Gastroenterology*, 2020, 20(1): p. 422.
- [6] Wan C et al., Development and validation of the general module of the system of quality of life instruments for chronic diseases and its comparison with SF-36. *Journal of Pain and Symptom Management*, 2011, 42(1): p. 93-104.
- [7] Barkun A, G Leontiadis, Systematic Review of the Symptom Burden, Quality of Life Impairment and Costs Associated with Peptic Ulcer Disease; *The American Journal of Medicine*, 2010, 123(4): p. 358-66.e2.
- [8] Artemieva MS et al., Psychosomatic Aspects and Treatment of Gastrointestinal Pathology; *Psychiatria Danubina*, 2021, 33(Suppl 4): p. 1327-1329.

