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Turkish validation of the Hernia-Specific Quality of Life Assessment Instrument

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ABSTRACT

Objective: In this study, we aimed to verify the validity of the Hernia Specific Quality of Life (HERQL) questionnaire, which measures functional performance and postoperative quality of life, in the Turkish language and also to evaluate the quality of life of our patients.

Patients and Methods: One hundred and one patients who underwent inguinal hernia repair at Kayseri City Training and Research Hospital, Department of General Surgery between July 2021 and September 2021 were prospectively included in this study. The HERQL questionnaire was administered to patients preoperatively, then on the first day and at the third month postoperatively. Quality of life, summative pain and satisfaction scores were determined as a result of the data. These scores were used for the validation of the questionnaire in Turkish. Additionally, preoperative and postoperative scores were compared with each other.

Results: The internal consistency analysis was performed and it was determined that the questionnaire had good reliability in all scales. Confirmatory factor analysis revealed that all values had a good fit to the established model.

Conclusion: Our finding suggest that the HERQL questionnaire has a good reliability and can be used in the Turkish population.

Keywords: Groin hernia, HERQL, Quality of life, Validation

1. INTRODUCTION

The protrusion of some of the organs in the abdomen from congenital or acquired weak points is called a hernia. Both inguinal hernias and femoral hernias are called groin hernias [1]. A groin hernia is a hernia that occurs below the level of the anterior superior iliac spines of the anterior abdominal wall and is one of the most common diseases requiring surgical intervention in general surgery practice [2]. The lifetime risk of developing an inguinal hernia is 27% for men and 3% for women. The most important risk factors for developing an inguinal hernia are age, gender, and external risk factors such as works requiring high physical effort [3]. Although, surgery is the only definitive treatment method for inguinal hernia, there is no clear consensus regarding treatment in asymptomatic patients. There are conventional, prosthesis (anterior), and prosthesis (endoscopic) techniques for the treatment of groin hernias [4].

In a study conducted in Taiwan in 2017, the "Hernia Specific Quality of Life Assessment Instrument (HERQL)" questionnaire was put forward and the quality of life of patients with hernia repair was evaluated. The HERQL questionnaire presented in this study consists of 20 questions and aims to evaluate the quality of life, summative pain, and satisfaction scores of the patients. Quality of life and pain questions were asked preoperatively and at the 3rd postoperative month, while satisfaction questions were asked on the 1st postoperative day and at the 3rd postoperative month. We aimed to enhance the quality of life of patients with inguinal hernia repair by providing an assessment instrument specified for inguinal hernia patients [5].

In our study, we aimed to adapt HERQL questionnaire into Turkish and evaluate the validity of the Turkish version by applying it to patients who underwent groin hernia repair.

2. PATIENTS and METHODS

For the creation of the Turkish version of the HERQL questionnaire, the principal researcher of the HERQL study, Dr. Ching-Shui Huang, was contacted and written permission was obtained for the research.

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The translation phase of the questionnaire was done according to the guidelines proposed by Guillemin and Beaton [6, 7]. The questionnaire was translated from English to Turkish by an English teacher and a translator whose native languages are Turkish and who are fluent in English. Then, the Turkish questionnaire was translated back into English by an English teacher and a translator who were not included in the first translation. These translations were evaluated by five general surgery specialists who spoke English, and the Turkish translation was finalized.

Our study was carried out with the approval of the University of Health Sciences, Kayseri City Training and Research Hospital Ethics Committee (date 01.07.2021, approval number 429). Patients who underwent hernia repair with mesh due to groin hernias at the Kayseri City Training and Research Hospital General Surgery Clinic between 1 July 2021 and 15 September 2021 were included. In the power analysis performed to determine the sample size, the power of the study was calculated as 0.80 for 100 patients. A Paha® 15x15 cm polypropylene mesh (Altaylar Medical, Ankara, Turkey) was used in all patients.

Hernia Specific Quality of Life is a 20-question questionnaire. Questions 2, 8, 9, 11, 12, and 13 evaluate quality of life, questions 1, 3, 4, and 5 evaluate pain, and questions 15, 17, 18, 19, and 20 evaluate post-operative satisfaction. The other five questions assess activity restriction and feelings of discomfort. Quality of life, summative pain, and satisfaction scores were additive sums of the relevant results. A higher quality of life score meant more activity restriction due to hernia-induced discomfort and a high summative pain score meant more pain felt by patients at various levels of physical activity. However, a high satisfaction score was associated with a high level of satisfaction after surgery. In the first stage of the questionnaire, for the first 14 questions (quality of life and summative pain) face-to face interviews were conducted the day before the surgery and the last 6 questions (satisfaction) were asked on the first postoperative day, and thus the first measurement scores were obtained. In the second stage, third postoperative month, the entire questionnaire was asked again in telephone interviews. Patients with mental motor development disorders, rheumatologic diseases that may cause chronic pain, those who had difficulty in understanding and answering the questionnaire, those who had emergency surgical treatment due to incarceration or strangulation, and those who could not be reached by phone for the third postoperative month evaluation were excluded from the study. Written informed consent was taken from all participants.

The index study was conducted with a total of 183 patients, 22 laparoscopic and 161 open, whereas in our study, patients were not divided into groups according to surgical techniques. A total of 124 patients were included in our study. Twenty-three of these patients were excluded from the study because they could not be reached during the third postoperative month phone call, and the study was completed with a total of 101 patients.

Statistical analysis

SPSS (SPSS, Version 26, SPSS Inc., Chicago, IL, USA) program was used in the evaluation of the data. Categorical measurements were expressed as numbers and percentages, and numerical measurements as mean and standard deviation (median and minimum-maximum where necessary). Afterwards, the IBM SPSS AMOS 26 (Arbuckle, J. L. (2019). Amos (Version 26.0) [Computer Program]. Chicago: IBM SPSS) program was used to conduct the Cronbach's alpha (α) test to determine the internal reliability of the scales [8]. In addition, convergent and discriminant validity tests and confirmatory factor analysis (CFA) were applied in the study. The Shapiro-Wilk test was used to determine if the calculated scale scores had a normal distribution. Accordingly, the Wilcoxon rank test was used to determine the differences between the preoperative and postoperative findings of the scale scores. In statistical calculations, the significance level was taken as $p<0.05$.

3. RESULTS

One hundred and one patients were included in the study. Of these patients, 95 (94.1%) were male. The mean age was 54.5±13.6 years and the mean body mass index was 26.1±3.6. Of these patients, 37 (36.6%) were smokers, 37 (36.6%) had comorbidity, and 26 (25.7%) were found to have developed postoperative complications (seroma, hematoma, urinary retention, and chronic pain).

Among the patients, 79 (78.2%) had a unilateral hernia and 22 (21.8%) had bilateral hernias. Of the patients, 87 (86.1%) were operated on due to a newly diagnosed hernia, and 14 (13.9%) patients were operated due to recurrent hernias (Table I).

Table I. *Examination of descriptive features*

	Frequency (n)	Percentage (%)
Sex		
Male	95	94.1
Female	6	5.9
Smoker		
No	64	63.4
Yes	37	36.6
Side		
Unilateral	79	78.2
Bilateral	22	21.8
Recurrence		
New diagnosed	87	86.1
Recurrent	14	13.9
Comorbidities	37	36.6
Complications	26	25.7
	Mean ± SD	**Median (Min-Max)**
Age	54.5±13.6	57 (19-78)
Height (cm)	171.5±7.2	172 (151-187)
Body weight(kg)	76.5±11	75 (53-105)
BMI	26.1±3.6	26 (18-35)

BMI: Body Mass Index, SD: Standard Deviation, Min: Minimum Max: Maximum

As shown in Table II, when the preoperative and postoperative reliability of the quality of life and summative pain scales used in the study, and the first and second measurement reliability levels of the satisfaction scale were evaluated, it was determined that the Cronbach's alpha coefficients of the scale scores were reliable and at a high level.

Table II. *Reliability coefficients of scale dimensions*

	Item count	Mean ± SD	Cronbach's Alpha Coefficient	Reliability Value	Normality Test (Shapiro-Wilk)
Preoperative quality of life	6	16.4±6.0	0.707	Reliable	0.012**
Postoperative summative pain	4	13.9±10.7	0.805	High	<0.001**
First measurement satisfaction	5	9.1±1.8	0.739	Reliable	0.005**
Postoperative quality of life	6	8.3±2.5	0.731	Reliable	<0.001**
Postoperative summative pain	4	2.5±4.5	0.837	High	<0.001**
Second measurement satisfaction	5	8.2±2.9	0.793	Reliable	<0.001**

***p<0.001*

All goodness-of-fit indices were reached in the final CFA, including the goodness-of-fit index (GFI), root mean square error of approximation (RMSEA), and PCLOSE. It was found that the chi-square/degrees of freedom (X2 / Df) (1.155), GFI (0.904), adjusted goodness of fit index (AGFI) (0.854), incremental fit index (IFI) (0.963), Tucker-Lewis Index (TLI) (0.953), comparative fit index (CFI) (0.961), RMSEA (0.039) and PCLOSE (0.683) values met all the critera to fit the established model (Table III).

Table III. *GFIs for CFA in the established model*

Model Fit Indices	Proposed Criteria	Default Model
X^2 / Df	1:3	1.155
GFI	> 0.90	0.904
AGFI	> 0.80	0.854
IFI	> 0.90	0.963
TLI	> 0.90	0.953
CFI	> 0.90	0.961
RMSEA	< 0.50	0.039
PCLOSE	> 0.50	0.683

X2 / Df: Chi Square / Degrees of Freedom, GFI: Goodness of Fit Index, AGFI: Adjusted Goodness of Fit Index, IFI: Incremental Fit Index, TLI: Tucker – Lewis Index, CFI: Comperative Fit Index, RMSEA: Root Mean Square Error of Approximation, PCLOSE: Probability of Close Fit

As presented in Table IV, all factor loadings in this study were greater than 0.50 and all critical ratios were above 1.96. The composite reliability (CR) of each variable was more than 0.70 (0.747-0.835), and the average variance (AVE) of each variable was found to be more than 0.50 (from 0.776 to 0.797). In light of these findings, it was determined that convergent validity was achieved in our study.

Table IV. *Examination of the findings of convergent validity*

Variable	Question	Factor load	Critical ratio (t-value)	CR	AVE
Quality of Life	2	0.891	20.086	0.747	0.792
	8	0.899	14.852		
	9	0.877	13.397		
	11	0.912	15.150		
	12	0.944	16.874		
	13	0.886	20.031		
Summative Pain	1	0.889	16.628	0.768	0.776
	3	0.815	19.360		
	4	0.907	13.334		
	5	0.869	13.497		
Satisfaction	15	0.920	13.245	0.835	0.797
	17	0.859	14.292		
	18	0.919	15.642		
	19	0.897	17.343		
	20	0.885	15.616		

CR: Composite reliability, AVE: Average varience extracted

As shown in Table V, the second measurement values of the quality of life, summative pain, and satisfaction scale scores were lower than the first measurement values (p<0.001; p<0.001; p=0.011, respectively).

Table V. *Differences in scale scores between the two evaluations*

	1st Measurement Mean ± SD	2nd Measurement Mean ± SD	p
Quality of Life	16.4±6.0	8.2±2.9	**<0.001****
Summative Pain	13.9±10.7	2.5±4.5	**<0.001****
Satisfaction	9.1±1.8	8.3±2.5	**0.011***

**p<0.05, **p<0.001*

In our study, the complication rate was found to be 25.7% in patients. In the HERQL study, chronic pain was detected in 6.6% of patients after surgery, hematoma in 3.8%, seroma in 3.3%, urinary retention in 2.7%, wound infection in 2.2%, and sepsis in 0.6% [5]. In our study, chronic pain was found in 10.89% of the patients, urinary retention in 8.91%, seroma in 7.92%, and hematoma in 2.97%. Sepsis and wound infection were not observed in the patients included in our study (Table VI).

Table VI. *Complication rates in the index HERQL study and the Turkish validation study*

	Index Study	Validation Study
	n (%)	n (%)
Chronic pain	12 (6.6)	11 (10.9)
Hematoma	7 (3.8)	3 (3)
Seroma	6 (3.3)	8 (7.9)
POUR	5 (2.7)	9 (8.9)
Wound infection	4 (2.2)	0 (0)
Sepsis	1 (0.6)	0 (0)

POUR: Postoperative urinary retention

4. DISCUSSION

Groin hernia repair is one of the most common surgical operations in the world. Seventy-five percent of hernias are groin hernias and the prevalence in the general population is 3.6%. The surgical requirement for hernia repair is that it is simple, easy, and applicable. What is important for the patient is comfort in the early period and minimizing recurrences [9]. Postoperative pain is an important complication of hernia repair and may affect daily physical activity. Although, the pain usually disappears on its own without the need for additional treatment, some patients may experience chronic pain [10].

The definition of quality of life has been made by the World Health Organization as "perceiving one's own life in a culture and value system according to one's own goals, expectations, standards, and interests" [11]. The best way to measure quality of life is through self-administered questionnaires [12]. It has been shown that disease-based questionnaires are superior to general quality-of-life questionnaires in detecting problems and determining changes resulting from treatment, especially in patients undergoing surgical treatment [13]. In a study, Carolinas Comfort Scale, which is a hernia-specific questionnaire, and the SF-36 (Short Form-36) questionnaire, which shows the general health status, were applied to the patients. The findings have shown that there are no significant changes in the mental health and general health areas of the SF-36, while there are significant changes in the postoperative Carolinas Comfort Scale in the patients [14].

Various disease-based questionnaires were conducted for patients who had hernia repair surgery. The Carolinas Comfort Scale, which assesses quality of life, was published in 2004 and was translated and validated in 28 different languages [14, 15]. In 2011, Core Outcome Measure Index (COMI)-hernia was developed to evaluate the quality of life and chronic pain in hernia patients [16]. Similar to these questionnaires, there is an Inguinal Pain Questionnaire that evaluates postoperative inguinal pain [17].

The Carolinas Comfort Scale is a test that evaluates quality of life in eight different positions [15]. The fact that it was translated into 28 languages in 45 countries shows the easy applicability of the questionnaire. In a validation study conducted in Lithuania, it was observed that the quality of life in the questionnaire results was high if the second application of the questionnaire was made at the third postoperative week. In case of an earlier application for the second test, the possibility of patients remembering the questions and this resulting in erroneous outcomes has been reported [14]. In our study, the second measurement period was determined to be three months. Thus, sufficient waiting time has passed for the patients not to remember the questionnaire questions and to evaluate the problems that may develop postoperatively.

The COMI-Hernia study is a long-term follow-up study of patients' pain levels and quality of life after surgery. After the preoperative questionnaire was applied to the patients, the questionnaire was applied again at the postoperative 3rd, 6th, 12th, 24th, and 36th months. [16]. The Inguinal Pain Questionnaire is a modification of a questionnaire prepared by Kehlet et al., in 2002 [18]. This questionnaire only assesses postoperative groin pain. For this reason, the authors stated that the difference between surgical pain and other causes of inguinal pain such as adductor tendinitis, osteoarthritis, and idiopathic pain could not be evaluated with this questionnaire [16, 17]. Additionally, its clinical applicability is lower than other questionnaires. The reason for this is that pain is a personal phenomenon, and therefore measurement and validation are problematic in this questionnaire, which only evaluates pain [17].

Hernia Specific Quality of Life questionnaire was created in 2017 as a questionnaire that includes a 4-item summative pain score that measures pain and discomfort caused by various strenuous activities to determine the quality of life of people who underwent hernia surgery. Apart from symptomatic and functional areas, it also evaluates post-operative satisfaction. It was created to increase the quality of life of patients and it was stated that it would serve as a guide for future studies [5]. The translation and validation of this questionnaire into any language are not available.

In the HERQL study, the patients preoperatively reported more severe hernia protrusion, more pain and worse activity restriction during light and heavy exercise, and overall poor health when compared to patient reports after surgery. Repeated measurement of summative pain scores showed a gradual decrease in total pain scores from preoperative levels and over the following three months. For this reason, it has been argued that it should be adapted and used to improve the quality of life of patients after hernia surgery and to eliminate potential complications such as chronic, non-disabling pain [5].

As a result of our research, the internal reliability of the Turkish version of the HERQL questionnaire was measured to be high (Cronbach's alpha value ≥0.7 in all scores). When confirmatory factor analysis was performed, it was seen that the Turkish questionnaire provided adequate consistency in all values. In light of these findings, it was concluded that the Turkish version of the HERQL questionnaire is suitable for clinical use.

Of the 183 people in the HERQL study, 163 (89%) were male, and 16.9% were operated for recurrent hernias [5]. A total of 101 patients who underwent groin hernia operations were included in our study, and 94.1% of these patients were male. 13.9% of

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Marmara Med J 2025;38(1): 43-48

the patients were operated due to recurrent hernia. In addition, when the quality of life, summative pain, and satisfaction scores of the patients were compared between the two measurements, it was seen that there was a significant improvement in all scores (Table V). According to these findings, it was concluded that patients who underwent inguinal and femoral hernia repair surgery in our clinic had less pain in the third postoperative month compared to the preoperative period, and their quality of life increased.

Postoperative neuralgia, which is rarely encountered after groin hernia repair and causes chronic pain, may be due to surgical traumas and fibrosis around the mesh, as well as due to nerve traction [19]. Postoperative urinary retention (POUR) is a complication that has been reported to occur between 0.4% and 41.6% after inguinal hernia repair, many factors are blamed among the risk factors and may lead to undesirable conditions such as patient discomfort and urinary catheter infection [20]. Conditions such as seroma and hematoma resulting from surgical dissection may be detected in most patients and are often mistaken for hernia recurrence [21]. In the literature, the average complication rate after hernia surgery ranges from 5% to 18% [22]. In our study, the complication rate was 25.7%, and these complications, along with those in the index HERQL study, are shown in Table VI. The differences between the two groups may result from various factors, including the conditions of the clinic where the surgery was performed, the experience of the surgeon, and the surgical technique applied.

Conclusion

In the HERQL scale validation study, it was determined that the internal reliability analysis was reliable at a good level and it was found to be suitable for use in studies. With this result, we proved that the HERQL questionnaire is usable in our population. In addition, when the pre – and postoperative quality of life, summative pain, and satisfaction scores were compared, it was observed that there was a statistically significant improvement in patients who had hernia surgery in all scales.

Compliance with Ethical Standards

Ethical approval: Our study was carried out with the approval of the University of Health Sciences, Kayseri City Training and Research Hospital Ethics Committee (date 01.07.2021, approval number 429).

Conflict of interest: The authors declare that there is no conflict of interest.

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Authors contributions: YS: Constructed the hypothesis and planned the article's methodology, RMF: Took responsibility for data collection and writing the final manuscript, SC: Performed the statistical calculations, YD: Organized and supervised the course of the progress. All authors have read and approved the manuscript.

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