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Validity and reliability of the Turkish version of the EmPHasis-10 questionnaire in patients with pulmonary hypertension

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Abstract

Rationale, aims, and objectives: The aim of the study was to evaluate the reliability and validity of the Turkish version of the EmPHasis-10 questionnaire to ensure cultural adaptation.

Methods: This study involved translation, back translation, and cross-cultural adaptation. One hundred and one patients who were diagnosed as having pulmonary hypertension (PH) for at least 6 months were evaluated using the Turkish version of EmPHasis-10. Turkish version of the Minnesota Living with Heart Failure Questionnaire (MLHFQ) was used as gold standard to assess the validation of the Turkish version of the EmPHasis-10 questionnaire. Relationship between MLHFQ and EmPHasis-10 was analysed using Spearman correlation analysis to assess the validation. Cronbach alpha (internal consistency) and exploratory factor analyses were used to assess the questionnaire's reliability.

Results: The statistical analysis showed that the EmPHasis-10 questionnaire showed a high validity with MLHFQ ($r = 0.85$) ($P = 0.001$). Reliability analysis showed that EmPHasis-10 had a high level of Cronbach alpha ($\alpha = 0.98$) and internal consistency (ICC = 0.97).

Conclusions: The Turkish version of EmPHasis-10 is a quality of life questionnaire specific to PH. It has a high-level validity and reliability questionnaire that can be used by researchers and physicians.

KEYWORDS
pulmonary hypertension, quality of life, reliability, validity

1 | INTRODUCTION

Pulmonary hypertension (PH) is defined as the mean pulmonary artery pressure 25 mmHg or more at rest measured by right heart catheterization. The clinical classification of PH includes the PH subgroups, and the most recent classification system consists of five categories. Precapillary PH (pulmonary wedge pressure ≤ 15 mmHg) includes clinical groups 1 (pulmonary arterial hypertension), 3 (PH due to lung

diseases and/or hypoxia), 4 (chronic thrombo-embolic PH), and 5 (PH with unclear and/or multifactorial mechanisms), and postcapillary (pulmonary wedge pressure > 15 mm Hg) PH corresponds to clinical group 2 (PH due to left heart diseases).[1]

At the beginning of the disease process, symptoms such as shortness of breath, weakness, or dizziness during exercise may be seen in most patients.[2] Patients report that PH has a very important effect in their daily lives.[3] Current treatment options for patients with PH have

led to better outcomes for symptom management and disease progression, but functional and haemodynamic impairments are still extensive and lead to worsening of quality of life in many patients.[4] Patients with PH have decreased respiratory muscle strength, exercise capacity, and physical activity.[5,6] After the diagnosis of PH, patients try to cope with the mixed feelings of understanding and accepting the truth. The complex nature of PH, the uncertainty of the future, and the insufficiency of treatment may reveal symptoms associated with depression such as distress, not sustaining regular social activities, and worsening of sleep quality.[7] Most patients report fatigue and dyspnoea, which affects their lives. These symptoms make stair climbing difficult, shorten walking distances, affect their emotional state, and require frequent rest during daily work, all of which lead to a decrease in the quality of life.[8-10]

Many health-related quality of life (HRQoL) measures have been developed and used to question how patients' quality of life is affected. The Short Form 36 (SF-36),[11] Nottingham Health Profile (NHP),[12] and EuroQol (EQ-5D)[13] are general health questionnaires frequently used in patients with PH.[14-16] The Cambridge Pulmonary Hypertension Outcome Review (CAMPHOR),[17] Living with Pulmonary Hypertension (LPH),[18] and Pulmonary Arterial Hypertension-Symptoms and Impact (PAH-SYMPACT)[19] questionnaires are PH-specific HRQoL questionnaires.[20] However, there is no Turkish translation or validity and reliability of these disease-spesific surveys in Turkish for patients with PH.

The Turkish version of the Minnesota Living with Heart Failure Questionnaire (MLHFQ) is the only Turkish HRQoL questionnaire for patients with PH. It is a 21-question survey that has high validity and reliability.[21] It has also been reported as a significant predictor of outcome in patients with PH.[22] However, it has demonstrated validity and reliability for use in a research context.[23] It is difficult to apply in a clinical practice because it contains relatively many number of questions and takes a long time. The EmPHasis-10 is a short questionnaire for assessing HRQoL in pulmonary arterial hypertension.[23] It was developed to assess patients with PH in the clinic. It is a 10-question survey that has high validity, reliability, and sensitivity for relevant clinical parameters such as psychological distress, functional exercise capacity, and dyspnoea. It is easy to score. The translation and validation of the EmPHasis-10 questionnaire in Turkish was necessary to have an alternative HRQoL questionnaire for patients with PH that could be implemented in a short time and easily used and scored by academics and physicians in clinical practice.

2 | METHOD

2.1 | Study sample

Our study was conducted with volunteer participants who were followed up by the Istanbul University Istanbul Medical Faculty, Department of Chest Diseases, and Istanbul University Cardiology Institute with the cooperation of the Division of Physiotherapy and Rehabilitation of Istanbul University Faculty of Health Sciences between September 2016 and May 2017.

2.2 | Measures

Turkish version of the **MLHFQ**[21] was used to assess the validation of the Turkish version of the EmPHasis-10 questionnaire.

Functional exercise capacity and psychological distress (anxiety and depression) were assessed to reveal clinical features associated with quality of life. The Six-Minute Walk Test (6MWT) was performed to determine the functional exercise capacity of the patients, and Turkish version of the Hospital Anxiety Depression Scale (HADS)[24] was used to assess patients' anxiety and depression level.

2.2.1 | Sociodemographic data form

Questions related to age, sex, body mass index, education status, marital status, occupation, smoking status, PH diagnosis date and follow-up period, clinical classification, and World Health Organization (WHO) functional classification (FC) are included in the patient form.

2.2.2 | EmPHasis-10

EmPHasis-10 is a quality of life questionnaire specific to patients with PH that consists of 10 questions developed by Yorke et al.[23] The survey includes significant effects of PH disease such as shortness of breath, fatigue and lack of energy, and concerns about the effects of social relations. The questionnaire is evaluated using a Likert scale. Each question has a score in the range of 0 to 5. The total score that can be taken from the questionnaire is in the range of 0 to 50, and high scores indicate poor quality of life.[23] The EmPHasis-10 survey has validity and reliability in seven languages: Dutch, Spanish, English and French (Canada), French (France), German, and Italian, but, to our knowledge, none of the translation studies have been published.[25]

2.2.3 | Minnesota Living with Heart Failure Questionnaire

The MLHFQ is a quality of life questionnaire that consists of 21 questions specific to patients with PH.[22] There are the 21 questions that investigate dyspnoea, anxiety and depression, fatigue, and peripheral oedema. The lowest score on the scale is 5, the highest score is 105, and score of 5 indicates that the quality of life is good and 105 means the quality of life is poor. Turkish version of the MLHFQ's was found reliable and valid in 2013 by Uzunhasanoglu.[21] The Turkish version of the MLHFQ is the only Turkish HRQoL questionnaire for patients with PH. Therefore, the Turkish version of the MLHFQ[21] was used to assess the validation of the Turkish version of the EmPHasis-10 questionnaire. Relationship between MLHFQ and EmPHasis-10 was analysed to assess the validation. The correlation coefficient was accepted as ≥0.75 for high validity.

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2.2.4 | Hospital Anxiety and Depression Scale (HADS)

Psychological distress was assessed to reveal clinical features associated with quality of life. The Turkish version of HADS[24] was used to assess the patients' psychological distress. HADS was developed to detect patients at risk of anxiety and depression. The scale consists of 14 questions: seven questions (numbers 1, 3, 5, 7, 9, 11, and 13) assess anxiety and seven questions (numbers 2, 4, 6, 8, 10, 12, and 14) assess depression symptoms. The lowest score that patients can achieve from both subscales is 0 and the highest score is 21. Patients are evaluated according to the following cut-off points: 0 to 7 (normal), 8 to 10 (the verge of abnormal), 11 to 21 (abnormal).[26]

2.2.5 | Six-Minute Walk Test

Functional exercise capacity was assessed to reveal clinical features associated with quality of life. The 6MWT was performed to determine the functional exercise capacity of the patients. The test was performed according to the American Thoracic Society (ATS) guideline statements.[27] Patients walked for 6 minutes at daily walking speed along a corridor with a minimum of 30 m in length. The distance was calculated in terms of meters, also expressed as a percentage of the expected value.[28]

2.3 | Reliability and validity stages of the EmPHasis-10 questionnaire

After obtaining permission to conduct the translation and validation of the questionnaire from the developer at Manchester University, who developed the questionnaire, licence protocols were signed in order to determine the validity. Linguistic validation was conducted in accordance with the procedure given by the developer.

The survey was translated from English to Turkish twice by the researcher who is a health professional and a blinded independent researcher who is a certified medical translator. A third independent and blinded researcher evaluated these two Turkish translations. The translated Turkish version of the questionnaire was translated back into English by another researcher who is a native English speaker and understands and speaks Turkish fluently. This translation was compared with the original version of the questionnaire. There was no difference in the comparison.

Before the formal survey, the pre-final Turkish version of the instrument was used for a pilot test. The Turkish translation was primarily applied to five patients with PH for the detection of unintelligible questions or words. We asked patients the following questions: "Is there a question you do not understand?" "Are there any words you do not like?" The questionnaire was not modified as a result of the patients not experiencing any problems, and the final version of the questionnaire began to be used for the study.

To assess the validation of the Turkish version of the EmPHasis-10 questionnaire, MLHFQ was used, which is the only PH-specific HRQoL questionnaire available in Turkish. The Turkish version of EmPHasis-10 was tested again after 1 week for test-retest. As a result of the test-retest, the reliability level of the Turkish version of EmPHasis-10 was determined.

2.4 | Participants and data collection

In validity and reliability studies, the sample size can be calculated as two to 20 patients per question.[29] Our study was planned to have 10 patients for each question in the survey and a total of 100 patients. We included patients who were diagnosed as having PH for at least 6 months through right heart catheterization by a physician and were followed up in the PH outpatient clinics. Patients who were aged 18 years or over were included in the study. Cognitive or speech impaired patients, patients with difficulty in understanding Turkish, and patients who had undergone successful pulmonary endarterectomy operations whose pulmonary artery pressure had dropped to normal values were excluded from the study (Figure 1).

Participants who met the inclusion criteria were selected from related hospitals within the PH clinics. Data were collected by the same researcher at the patients' routine clinic visits. Sociodemographic information of the patients was obtained, and the 6MWT was performed. EmPHasis-10, MLHFQ, and HADS questionnaires were completed by the patients.

2.5 | Statistical analysis

The analysis of the data was performed using the IBM Statistical Package for the Social Sciences (SPSS) version 22.0 for Windows program. Continuous data were presented as mean and standard deviation (SD), and categorical data were presented as number (n) and proportions (%). The fitness of data to normal distribution was tested using Kolmogorov-Smirnov analysis. In order to determine the validity of the questionnaire, Spearman correlation analysis was used to determine the relationship between questionnaires and Kruskal-Wallis analysis for criterion validity. Correlation coefficients were evaluated using the following criteria: There is no or a very weak relationship (0-0.25), a weak-medium relationship (0.25-0.50), a good relationship (0.50-0.75), and a very good relationship (0.75-1.00). For the reliability analysis of the questionnaire, Cronbach alpha coefficient was used. The results were evaluated at 95% confidence intervals and significance at $P < 0.05$ level. Cronbach alpha coefficient was evaluated using the following criteria: $0.00 \leq \alpha < 0.40$, the scale is not reliable; $0.40 \leq \alpha < 0.60$, the scale has low reliability; $0.60 \leq \alpha < 0.80$, the scale is highly reliable; $0.80 \leq \alpha < 1.00$, the scale was interpreted as having a high level of reliability.[30]

3 | RESULTS

A total of 126 patients with PH were assessed in terms of inclusion criteria in this study. One hundred and one patients who met the criteria were included, and 25 were excluded from the study because they did not meet the inclusion criteria. The average age of
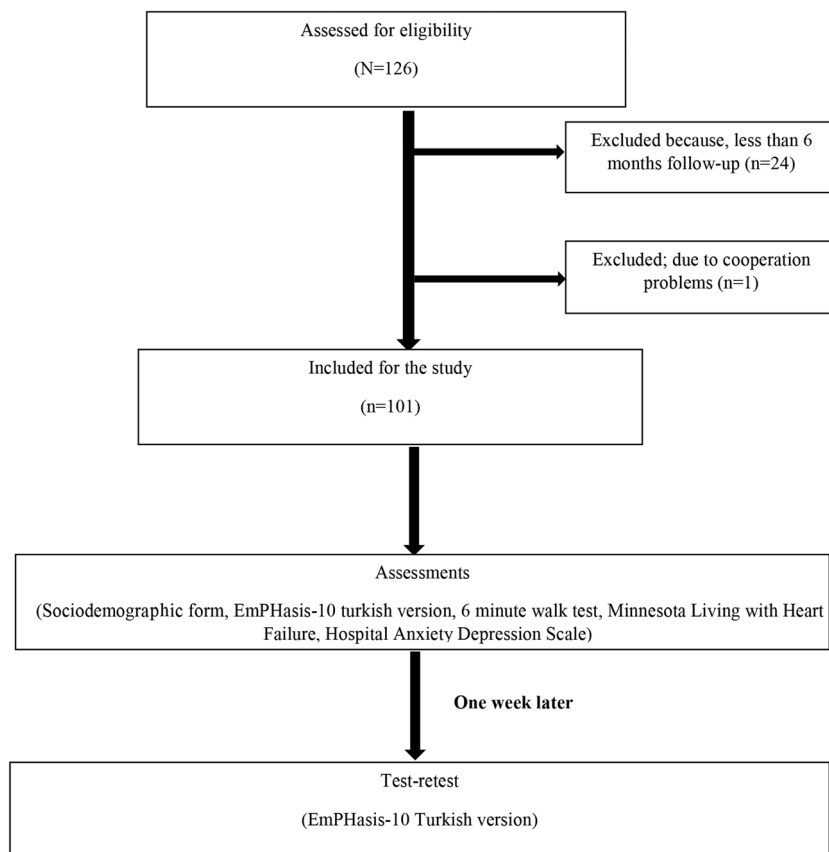
FIGURE 1 Flow diagram

participants was 52.5 ± 16.1 years with large proportion (81.2%) of female patients. The mean follow-up period of the patients was 54.1 ± 63.6 months. The majority (73.3%) of the participants had elementary school level education, 68 (67.3%) patients were unemployed, and only 13 (12.9%) were working. In our study, the majority of the patients were WHO FC II (44.6%) and III (39.6%). A large number of participants were group I PH patients (62.4%) followed by group IV chronic thromboembolic PH (32.7%) patients according to the clinical classification (Table 1). Six-minute walk distance and patient-reported outcome results are indicated in Table 2.

3.1 | Validity

In the validity analysis, Spearman correlation analysis was used because the data were not normally distributed. The coefficient correlations of the EmPHasis-10 and MLHFQ quality of life questionnaires are shown in Table 3. EmPHasis-10 and MLHFQ showed strong correlation ($r = 0.85$, $P = 0.001$); therefore, validity of EmPHasis-10 questionnaire was considered as high.

The validity of EmPHasis-10 was also demonstrated using criterion validity. Criterion validity was conducted to examine the relationship of the EmPHasis-10 and MLHFQ scores with WHO FC. In the MLHFQ and EmPHasis-10, FC was seen to increase as the condition of the patients worsened (Table 4).

3.2 | Reliability

Test-retest reliability and internal consistency were found to be highly reliable for the Cronbach alpha value ($\alpha = 0.98$). Internal consistency is 0.97 compared with the 95% confidence interval. The Cronbach alpha values, internal consistency, and confidence intervals of items in Turkish version of EmPHasis-10 are given in Table 5.

4 | DISCUSSION

Our study showed that the Turkish version of EmPHasis-10 questionnaire was highly valid because of the strong correlation with MLHFQ and that it was reliable according to the Cronbach alpha and internal consistency result.

In the internal consistency assessment for each of the EmPHasis-10 questionnaire items, nine items had the same internal consistency result (0.83-0.94), and the internal consistency result of the second item, which questioned whether the patients experienced breathlessness during conversation, was the lowest with 0.62. The lowest internal consistency seems to be "highly reliable."

EmPHasis-10 was completed by Yorke et al.[23] It was necessary to develop the EmPHasis-10 questionnaire because CAMPHOR and LPH consist of multiple questions, the grading systems differ between subgroups, and they are time consuming in clinical practice. Yorke et al included 226 patients in their study whose demographic and clinical features were similar to those in the EmPHasis-10 Turkish version study.

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TABLE 1 Demographic and clinical variables of subjects

Variables	Mean ± SD/n (%)
Age, y	52.5 ± 16.1
Gender	
Female/male	82 (81.2%) /19 (18.8%)
BMI, kg/m^2	27.0 ± 5.7
Education	
Primary school	74 (73.3%)
High school	14 (13.9%)
College	13 (12.9%)
Marital status	
Married	84 (83.2%)
Single	17 (16.8%)
Employment status	
Unemployed	68 (67.3%)
Retired	20 (19.8%)
Full time work	13 (12.9%)
Smoking	
Yes	15 (14.9%)
No	86 (85.1%)
Follow-up period, month	54.1 ± 63.6
PAP mmHg (mean)	58.5 ± 26.6
WHO functional class	
I	16 (15.8%)
II	45 (44.6%)
III	40 (39.6%)
Aetiology of PH	
Group 1: PAH	63 (62.4%)
Idiopathic	29 (46.0%)
Congenital heart disease	22 (34.9%)
Connective tissue disease	12 (19.0%)
Group 2: PH left heart disease	1 (1%)
Group 3: PH lung	2 (2%)
Group 4: CTEPH	33 (32.7%)
Group 5: Neurofibromatosis and sarcoidosis	2 (2%)

Abbreviations: SD, standart deviation; PAP, pulmonary arterial pressure; WHO, World Health Organization; PAH, pulmonary arterial hypertension; PH, pulmonary hypertension; CTEPH, chronic thromboembolic pulmonary hypertension.

In the original article, the mean 6MWD was 336 ± 130 m.[23] The mean 6MWD was 374.6 ± 113.5 m in our study. Yorke et al[23] showed a weak-to-moderate correlation between 6MWD and EmPHasis-10 (r = 0.40, P = 0.001); this correlation in the Turkish version of EmPHasis-10 was lower, but it still showed a weak-to-moderate correlation (r = 0.29, P = 0.003).

In the original EmPHasis-10 study,[23] the MLHFQ survey was administered as the gold standard questionnaire as in the Turkish version of EmPHasis-10; there was a strong correlation between MLHFQ and the EmPHasis-10 questionnaire in both studies.

Yorke et al[23] found that the mean outcome of the HAD anxiety subgroup was 6.9 ± 4.4, and the depression subgroup was 6.3 ± 3.9. The original EmPHasis-10's HAD score data appear to be higher than

TABLE 2 Exercise capacity, anxiety-depression and quality of life data

	Minimum	Maximum	Mean ± SD
6MWD, m	35	595	374.6 ± 113.5
6MWD (predicted value as %)	8.4	110.3	68.0 ± 18.1
HADS			
Anxiety	0	20	3.9 ± 4.2
Depression	0	19	3.3 ± 3.7
MLHFQ	0	83	23.0 ± 19.6
EmPHasis-10 (first assessment)	0	45	14.5 ± 10.7
EmPHasis-10 (second assessment)	0	42	14.2 ± 10.7

Abbreviations: 6MWD, Six-Minute Walk Distance; HADS, Hospital Anxiety and Depression Scale; MLHFQ, Minnesota Living with Heart Failure Questionnaire.

TABLE 3 Correlations between quality of life questionnaires

		EmPHasis-10 (first assessment)	EmPHasis-10 (second assessment)	MLHFQ
EmPHasis-10 (first assessment)	r		0.97*	0.85*
	P		0.001	0.001
EmPHasis-10 (second assessment)	r	0.97*		0.87*
	P	0.001		0.001
MLHFQ	r	0.85*	0.87*	
	P	0.001	0.001	

Abbreviation: MLHFQ, Minnesota Living with Heart Failure Questionnaire.
*P ≤ 0.001.

TABLE 4 Criterion validity[a]

	WHO-FC I (n = 16)	WHO-FC II (n = 45)	WHO-FC III (n = 39)	P
MLHFQ	12.3 ± 8.1	20.4 ± 18.1	30.7 ± 22.0	0.004
EmPHasis-10	9.3 ± 7.7	12.7 ± 9.9	18.4 ± 11.6	0.01

[a]Data expressed as mean ± standard deviation. WHO-FC: World Health Organization Functional Class, MLHFQ: Minnesota Living with Heart Failure Questionnaire.

TABLE 5 Reliability

Item	α	ICC	95% CI
Total	0.98	0.97	0.96-0.98
1	0.96	0.93	0.90-0.95
2	0.76	0.62	0.49-0.73
3	0.96	0.93	0.90-0.95
4	0.95	0.91	0.87-0.94
5	0.90	0.83	0.75-0.88
6	0.96	0.92	0.89-0.95
7	0.96	0.93	0.90-0.95
8	0.97	0.94	0.91-0.96
9	0.96	0.93	0.90-0.95
10	0.97	0.94	0.91-0.96

Abbreviations: α, Cronbach alpha; ICC, intraclass correlation; CI, confidence interval.

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our data. It may be a consequence of lower anxiety and depression scores in our study than in that of Yorke et al.[23]

The Cronbach alpha coefficient was found to be highly reliable in our study, similar to the original survey.

5 | CONCLUSION

The Turkish version of EmPHasis-10 is a quality of life questionnaire with a high level of validity and reliability that is specific to PH and can be easily used by researchers and physicians.

AUTHOR CONTRIBUTION

Pinar Odevoglu: Literature search, data collection, study design, analysis of data, manuscript preparation, review of manuscript. Rengin Demir: Data collection, manuscript preparation, review of manuscript. Gulfer Okumus: Data collection, manuscript preparation, review of manuscript. M. Serdar Kucukoglu: Data collection, manuscript preparation, review of manuscript. Goksen Kuran Aslan: Literature search, data collection, study design, analysis of data, manuscript preparation, review of manuscript.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

ETHICAL APPROVAL

The study was approved by the Ethics Committee of Clinical Investigations of Istanbul University on 25.05.2016 (number 2016/604-09). The study was conducted according to Helsinki Declaration, information about the application has been made and signed.

INFORMED CONSENT

Informed consent was obtained from all individual participants included in the studies.

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