ORIGINAL ARTICLE

Translation and Validation of Leicester Cough Questionnaire for Cystic Fibrosis Patients

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ABSTRACT

Aim: To translate and validate Leicester cough questionnaire in Urdu language for patients with Cystic fibrosis.
Methods: It is a cross-cultural linguistic study. 150 participants were included in the study and Non probability convenient sampling was used. Inclusion criteria includes parents of children with CF, who understand Urdu, and have symptoms of chronic cough. Children with severe respiratory exacerbations were excluded. Data was entered using SPSS version 25 and same software was used for data analysis.
Results: It took 6 months to achieve an Urdu version of LCQ, which proved to be satisfactorily acceptable when administered to 150 subjects. The questionnaire showed acceptable internal consistency (Cronbach's alpha =0.916), test-retest reliability by Pearson correlation ranged from 0.203 to 0.99 and intraclass correlation coefficient value 0.2 to 0.9 showed high reliability.
Conclusion: Leicester Cough Questionnaire is a valid and reliable tool for assessing the impact of cough on quality of life in patients with Cystic fibrosis.
Keywords: Cystic fibrosis, Cough, Health related quality of life, Leicester cough questionnaire.

INTRODUCTION

Chronic cough is any cough that lasts for more than eight weeks, with no concomitant clinical findings, and remaining without a definitive diagnosis after the initial clinical evaluation. It is the most common symptom in clinical practice and such patients suffer considerable physical and psychological morbidity. Assessment and management are hampered by absence of well validated outcome measure[1].

The Leicester cough questionnaire was designed for the objective evaluation of chronic cough and its impact on daily life. It is a self-administered questionnaire composed of 19 items divided into three domains: physical (8 items), psychological (7 items) and social (4 items). The total score range is 3-21 and domain score range from 1-7; a higher score indicates a better quality of life[2].

The LCQ was developed using a multistep method divided into three phases: phase 1 (item generation); phase 2 (item reduction, allocation of items to domains, and validation of the questionnaire); and phase 3 (repeatability and responsiveness testing of final version of the questionnaire). The item reduction was based on questionnaire responses from 104 patients and concurrent validity was assessed in a separate 56 patients, 27 who had a cough sensitivity measurement[3].

Several researches have looked into the reliability of LCQ, and it has showed to have good measuring qualities. The test-retest reliability in stable patients is high (0.79- 0.93).Internal reliability, as assessed using Cronbach's alpha coefficients varied between 0.79 to 0.89[4]. The LCQ has been used in several clinical trials to evaluate treatment methods and how they affect HRQOL. It has been translated into several languages in Europe (Dutch, French, Polish, Portuguese and Spanish) and in Asia (Korean and Mandarin Chinese), and validated in groups of patients with diagnosis where chronic cough is a known issue, e.g. bronchiectasis, COPD and cystic fibrosis. Different methods were used to test the validity in these studies[4]. The assessment of health status is increasingly important in respiratory disease and has been extensively studied in asthma and chronic obstructive pulmonary disease by development of disease specific questionnaires. Very little is known about the effects of chronic cough on health status because of the lack of such validated questionnaires[3].

Cystic fibrosis is a chronic, progressive, genetic disease that affects the exocrine glands causing multiple organ damage in the respiratory tract, pancreas, liver, sweat glands and reproductive system. Pulmonary pathophysiology is characterized by an absent or defective cystic fibrosis transmembrane regulator protein (CFTR) function, which causes abnormal regulation of periciliary liquid volume, decreasing mucociliary clearance and causing mucus plugging and lung obstruction. Productive cough is the major symptom of CF that becomes chronic as the disease progress[5].

Clinical signs and a conclusively positive sweat chloride test are used to assess the existence of the CFTR gene mutation at position 508 (AF508). The detected incidence of the AF508 mutation among Pakistani children with CF in this early investigation is lower than the reported frequency among the Western Caucasian population. Further studies are needed to characterize the common genetic mutations in Pakistani children with CF[6].

The study aims to translate the Leicester cough questionnaire into Urdu for parents who are unable to understand or use it to determine whether their child has chronic cough caused by cystic fibrosis. Because Urdu is the common language that is spoken and understood by the majority of the population in Pakistan, and the current literature regarding its use in children with cystic fibrosis was lacking. It is feasible to increase the effectiveness of therapy, extend longevity, and lessen the financial cost of sickness by keeping track of health-related quality of life and the effects of coughing.

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MATERIALS AND METHODS

This was a Cross-cultural linguistic validation study conducted at Lahore College of Physical Therapy (LMDC) and Ghurki Trust and Teaching Hospital and Children Hospital, Lahore during July 2022 to December 2022 after permission. Non-probability convenient

sampling was used to collect the sample size which was determined by Dr.Wan Nor Arifin unit of biostatics and research methodology, University Saint Malaysia[7]. Parents and caregivers of CF patients who understand Urdu between Age 7 to 18 years from both Genders who were medically fit but with chronic cough was included in the study and Patients with secondary complications like severe respiratory exacerbations, Smokers, patients with other lung diseases (COPD, pneumonia, bronchiectasiswere excluded. The approval was taken via email from SS Birring for Urdu translation LCQ. The translation and cross-cultural modification of LCQ was executed using five steps in compliance with previously published guidelines and in accordance with international guidelines[8].

Forward Translation: The translation of LCQ was done by two native Urdu-speaking Pakistani translators. One of them was a medical doctor who was aware of the concept of this study, and the other was a native translator with foreign Nationality[9].

Synthesis: During this step, the original version of the scale along with translations 1 (T1) and 2 (T2) were synthesized to obtain a common translation version (T-12). Urdu. The full Urdu translation of LCQ (T-12) was completed at this stage[10].

Backward Translation: At this stage, the back translation of the Urdu-translated version into the Englishlanguage was managed. For this purpose, the help of two bilingual translators was taken. both were native translator and both had great command in Urdu and English Language[11].

Expert Review: The expert committee's role was to consolidate all the versions of the questionnaire and develop what would be considered the pre-final version of the questionnaire for fieldtesting.stages). As the committee of 10-20 Pediatric rehabilitation specialists was already aware of the purpose of the study, they compared both of the versions. After comparing the Urdu and English versions of the scale, it was further updated and edited by the members of the committee[12].

Pretesting: The pre-final translated version of LCQ, both English and Urdu, was then tested and final testing of LCQ was done in a sample of 150. Consent was taking from parents before testing.These findings were then evaluated by the expert committee of 10-20 Pediatric rehabilitation specialists[13]. Data was entered by using Statistical Package for Social Sciences (SPSS)version21and same software was used for data analysis, The study variables were presented in the form of descriptive statistics (tables). Ethically approved by the committee of Lahore college of Physical Therapy, LMDC. An informed consent was obtained from all the participants prior to the study.

RESULTS

Content validity: Content validation index using ABC of content validationby a panel of 10 experts[14] is as:

Items	Experts in Agreement	Content Validity Index (S-CVI)	Universal Agreement (UA)
1	10	1	1
2	9	0.9	0
3-4	10	1	1
5	8	0.8	0
6-18	10	1	1
19	9	0.9	0
Total	0.97	0.97	0.84

Internal consistency: The Cronbach alpha of questionnaire EHI after population testing was 0.916

Cronbach's Alpha	No. of Items
0.916	19

Test-retest reliability: The Test-Retest Reliability by Pearson correlation ranged from 0.203 to 0.999.

Domains	Pearson Correlation	Sig. (2-tailed)	n
Chest or stomach pain	0.863	0.000	150
Sputum production	0.986	0.000	150
Tired	0.999	0.000	150
Felt embarrassed	0.997	0.000	150
Felt anxious	0.993	0.000	150
Interfered with job	0.315	0.000	150
Enjoyment	0.503	0.000	150
Exposure to paints and fumes	0.401	0.000	150
Disturbed sleep	0.335	0.000	150
Coughing bout	0.248	0.002	150
Frustrated	0.481	0.000	150
Fed up	0.479	0.000	150
Hoarse voice	0.623	0.000	150
Indicate Serious illness	0.564	0.000	150
Something wrong	0.502	0.000	150
Interrupted conversation and calls	0.203	0.013	150
Annoyed partner, family or friends	0.475	0.002	150
Felt in control of cough	0.229	0.004	150
Have had a lot of energy	0.235	0.003	150

Intrarater and interrater reliability: The intra class correlation coefficient value 0.2 to 0.9 showed high reliability.

	Intra class Correlation	95% Confidence Interval	
		Lower Bound	Upper Bound
Single Measures	.223	.184	.272
Average Measures	.916	.896	.934

DISCUSSION

The purpose of my study was to translate LCQ in Urdu language to assess the impact of cough on quality of life in patients with cystic fibrosis. Permission was granted from the author to translate the questionnaire for public benefit and educational purpose. We translated this by using standard forward and backward method of translation by Beaton classification. It is showed by previous studies as well that backward translation is better than direct translation[8].

After the completion of translation procedure, content validation was performed with the help of 10 physiotherapists. When scale was translated successfully a pilot study was conducted along with test-retest phase to evaluate the efficacy of scale. Some minor revisions were made according to testing conclusion and then this questionnaire was applied on 150 patients with cystic fibrosis having chronic cough in children hospital as well as Ghurki trust and teaching hospital, Lahore.

The difference between original and translated version of LCQ was described by test analysis. Inter-class correlation coefficient resulted 0.223 for single measure and 0.916 for average measure. The Urdu version of LCQ shows similar results to the original version created by SS Birring. The original version showed good reliability in all domains and in total score; with Internal reliability, as assessed using Cronbach's alpha coefficients, varied between 0.79 and 0.89. The Urdu version however, obtained higher values in both coefficients.

Results showed that Urdu version of LCQ is a valid and reliable questionnaire for assessing the impact of cough on health related quality of life in children with cystic fibrosis, with high internal consistency and Cronbach's alpha 0.91 in testing phase while 0.97 in validation phase.

Previous studies on translation and validation of LCQ also showed good results. The Spanish version of LCQ showed high internal consistency with Cronbach's alpha 0.83 for the LCQ (total) and for each specific domain was: 0.82 LCQ (physical); 0.74 LCQ (psychological) and 0.62 LCQ (social)[5]. The Dutch version showed Cronbach's alpha coefficient between 0.77 and 0.9[15]. The Swedish version of the Leicester Cough Questionnaire demonstrated good construct validity as well as internal consistency with Cronbach's alpha coefficient of 0.97[4] and the Portuguese version also showed good results and was proved to be well accepted and understood by all of the respondents and was cross-culturally adapted for use in Brazil[16].

The majority of the research also made comparisons between the LCQ and other HLQOL questionnaires, and the findings of each study demonstrated that the LCQ is a trustworthy and valid tool for evaluating HLQOL. The measure of quality of life is arbitrary. It has been reported to assess cough objectively using a 24-hour registration of cough sounds. This technique has not yet been verified. For patients, the psychological and social effects of a chronic cough seem to be more important than the physical ones. As a result, we view the LCQ, a health status indicator, as the key factor to consider when assessing chronic cough. It exactly matches the patient's experience, and there are no commercially accessible, well-validated, trustworthy alternative measures to quantify the burden of chronic cough[15].

The translated version's generalizability is constrained because it was tested on a smaller group, hence a study should be conducted on a bigger population. The LCQ should also be translated in other languages spoken in Pakistan by minorities or who cannot understand Urdu language.

CONCLUSION

The Urdu version of Leicester Cough Questionnaire is a reliable and valid tool for assessing impact of cough on quality of life in patients with Cystic fibrosis.

Authorship and contribution declaration: Each author of this article fulfilled following Criteria of Authorship:
1. Conception and design of or acquisition of data or analysis and interpretation of data.
2. Drafting the manuscript or revising it critically for important intellectual content.
3. Final approval of the version for publication.

All authors agree to be responsible for all aspects of their research work.

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